AF/1615 #

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	:	Andrew Clark, et al.
Application No.	:	08/916,578
Filing Date	:	August 22, 1997
Title	:	**Pharmaceutical Compositions**
Group/Art Unit	:	1615
Examiner	:	Robert M. Joynes
Reference No.	:	21407.0001 (formerly 2553.004)

CERTIFICATE OF MAILING (37 C.F.R. § 1.8A)

I hereby certify that this correspondence is, on the date shown below, is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the below shown address.

Mary Helen Lopez

SUBMISSION OF APPEAL BRIEF

TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Assistant Commissioner for Patents
Box of Appeal
Washington, D.C. 20231

Commissioner:

Enclosed for filing are the original and two copies of applicant's Appeal Brief for this application.

☒ An extension of time to file the appeal brief is requested, and a Petition for Extension of Time and the fee are enclosed ($410.)
☒ Our check for $320.00 to cover the fee for the appeal brief is enclosed.
_____ Small entity claimed under 37 CFR 1.27.
_____ An oral hearing of the appeal is requested, and our check for $_____, the fee for the oral hearing is enclosed.

Authorization and Address for Correspondence:

☒ The Commissioner is authorized during the prosecution of this application to charge fees that may be required or credit any overpayment of fees to Deposit Account No. 501215, except for payment of patent issue fees required under 37 CFR § 1.18. Please show our above-referenced number with any credit or charge to our Deposit Account. **A copy of this letter is enclosed.**

Please address all correspondence to **Jon E. Hokanson, COUDERT BROTHERS LLP, 333 South Hope Street, 23rd Floor, Los Angeles, California 90071.**

Respectfully submitted,
COUDERT BROTHERS LLP

Date: March 25, 2003

By: Jon E. Hokanson
Reg. No. 30,069

COUDERT BROTHERS LLP
333 South Hope Street, Suite 2300
Los Angeles, California 90071
(213) 229-2900

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WRITTEN SUMMARY OF INTERVIEW

37 C.F.R. § 1.133

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Mary Helen Lopez

WRITTEN SUMMARY OF INTERVIEW

37 C.F.R. § 1.133

In accordance with 37 C.F.R. § 1.133 and Form PTOL-413 (Rev, 2-98), applicants provide a written record of the interview held on February 6, 2003, as follows:

1. Brief Description of Exhibit Shown.

Samples of the nedocromil sodium ophthalmic solution of finally rejected claims 10-13 were shown to the examiners during the interview. These samples were in the form of 8 single use containers (0.4 ml each) of the solution marketed by the assignee's exclusive licensee, Allergan, Inc. ("Allergan"), Irvine, California as its Alocril® brand nedocromil sodium ophthalmic solution for treatment of itching associated with allergic conjunctivitis.

2. Identification of Claims Discussed.

All pending claims 10-19 were discussed in general, with independent claim 14 specifically discussed.

3. Identification of Prior Art Discussed.

Only a single rejection was discussed, and that was discussed only in general and within the context of applicants' not surrendering any subject matter as a result of that rejection. The rejection referred to was

the rejection made on March 8, 1990, under 35 U.S.C. § 103 on the basis of the Fisons '722 publication, in application serial number 410,020.

4. Identification of Amendments Discussed.

No amendment was discussed.

5. Identification of Arguments Presented.

The undersigned presented arguments on why the final rejection should be withdrawn. After a brief summary of the Federal Circuit law on the recapture estoppel rule, and its exceptions, it was pointed out that all of the finally rejected claims fell within both of two exceptions to application of the recapture rule. First it was pointed out that applicants had not made any admission of unpatentability regarding the eye disease treatment subject matter of the rejected claims, that reliable evidence of record demonstrated that applicants considered the subject matter of the rejected claims to be patentable and these facts qualified as an exception to application of the recapture rule. Second, it was pointed out that the reissue claims are narrower in the treatable eye diseases aspect than was the corresponding rejected and cancelled claim; are broader in the active ingredient administration aspect than was the corresponding rejected and cancelled claim; and that these facts established a second exception to application of the recapture rule.

6. Identification of Any Other Pertinent Matter Discussed.

No other matter was discussed.

7. **General Results or Outcome of the Interview.**

The examiners stated that they would consider the appeal brief before making any decision in regard to the arguments presented.

Respectfully submitted,

COUDERT BROTHERS LLP

Date: March 25, 2003

By: _____
Jon E. Hokanson
Reg. No. 30,069

COUDERT BROTHERS LLP
333 South Hope Street, Suite 2300
Los Angeles, California 90071
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AGENDA FOR INTERVIEW OF FEBRUARY 6, 2003

This is an appeal form from the Final Rejection, dated June 28, 2002, of claims 10-19 in application 08/916,578 ("the '578 application"). The '578 application is for reissue of U.S. Patent No. 5,443,833 ("the '833 patent") issued on August 22, 1995, and entitled "Pharmaceutical Compositions". The present reissue application was filed on August 22, 1997, and thus the scope of the claims may be enlarged in comparison to the scope of the claims in the '833 patent, as permitted under 35 U.S.C. § 251 (1952), subject to the other requirement of §251 and the recapture estoppel doctrine.

I. INTRODUCTIONS AND BACKGROUND

→ All of the finally rejected claims are directed to a nedocromil sodium ophthalmic solution for treating a sub-genus of conditions and/or several species of conditions within the sub-genus.

→ The nedocromil sodium ophthalmic solution is presently sold under the registered trademark "Alocril®." (1) Sample; (2) product package; (3) package insert; and (4) PDR entry. Product is Rx. For demonstration purpose only. No intend to make of record and

no intend for examiner to rely on anything in the demonstration that is not in the patent application record.

→ Claim status:

Claims 1-3 and 10-19 are pending.

Claims 1-3 have been allowed.

Claims 4-9 have been cancelled.

Claims 10-19 have been finally rejected, in a communication dated June 28, 2002.

→ The sole ground of rejection is 35 U.S.C. § 251, specifically that claims 10-19 are " . . an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based . . .[citations omitted]." Final rejection dated June 28, 2002.

II. ISSUE ON APPEAL OF CLAIMS 10-19

Whether the doctrine of recapture estoppel was properly applied as the ground of rejection of claims 10-19.

III. SUMMARY OF INVENTION

The invention of the claims on appeal is a method of treatment of a sub-genus of disorders of the eye with and effective amount of nedocromil sodium in an ophthalmically acceptable formulation.

The invention of the claims on appeal is a small subset of the invention as described in the '833 patent. The invention as described in the '833 patent is a method of treatment of a genus of disorders [of the eye, of the nasal area, of the airway and of the colon, as described at column 1, line 34 through column 2, line 5 of the '833 patent]. See, '833 patent, at col. 1. line 42 through col. 2, line 5; and Examples 4 and 7, at column 4, lines 27-37; and column 7, line 16- through column 8, line 17.

Various concentrations, various routes of administration, various additives and various forms of packaging the aqueous solutions of the invention are described in the '833 patent. None of the details of these features of the invention are relevant to the issue on appeal, and therefore no need for discussion during the interview.

IV. GROUPING OF CLAIMS

The rejection has been applied to each of claims 10-19.

Claims 10-19 do not stand or fall together.

Claims 14-19 may considered together for two arguments: (1) no admission of unpatentability of these claims is in the record; and (2) these claims have been substantially narrowed in comparison the to broadest claim presented during prosecution of the original patent (broadest original prosecution claim was for six sub-generic groups of diseases; present broadest claim on appeal [claim 14] is for only four sub-generic groups of diseases).

Claims 10 and 15 are further narrowed to cover only one sub genus (conjunctivitis) of the six sub-genuses of diseases that were the subject matter of the broadest original prosecution claim.

Claims 13 and 16 are limited to cover only one species (seasonal allergic conjunctivitis) of one sub-genus (conjunctivitis).

Claims 12 and 17 are limited to cover only one species (allergic conjunctivitis) of one sub-genus (conjunctivitis).

Claims 11 and 18 are limited to cover only one species (vernal conjunctivitis) of one sub-genus (conjunctivitis).

VIII. REASONS WHY THE REJECTION IS IN ERROR

A. The Final Rejection Applied Only The General Rule Of The Doctrine Of Recapture Estoppel And Failed To Even Acknowledge The Existence Of Two Well-Known Exceptions To The General Rule; Miscellaneous Points Re Markush Claims

→ Well settled that in its broad form, the recapture estoppel doctrine prevents a patentee from regaining through reissue subject matter surrendered in an effort to obtain allowance of the patent claims. In the words of the Federal Circuit, claims that are "broader than the original patent claims in a manner directly pertinent to the subject matter surrendered during prosecution" are impermissible. *In re Clement*, 131 F.3d 1464, 1468, 45USPQ2d 1161, 1163 (Fed. Cir. 1997); *Ball Corp v. United States*, 729 F.2d 1429, 221 USPQ 289 (Fed. Cir. 1984).

→ Analysis of a recapture estoppel issue always involves comparison of the scope of at least three claims:

(1) the later reissue claim(s);

(2) the earlier (original) prosecution claim(s); and,

(3) the intervening issued patent claim(s).

→ Claim 14 of the '578 reissue application is broader than claim 1 of the '833 patent.

→ Claim 14 of the '578 reissue application is set forth, as follows:

> 14. A method of treatment of a disease selected from the group consisting of conjunctivitis, keratitis, allergic eyes, and anterior uveitis, which method comprises administering to the eye an effective amount of an ophthalmically acceptable aqueous pharmaceutical solution containing the active ingredient 9-ethyl-6, -dihydro-4, 6-dioxo-10-propyl-4H-pyranol (3,2) quinoline-2, 8-dicarboxylic acid, or a pharmaceutically acceptable salt thereof.

Amendment mailed July 9, 2001, at 1.

→ Reissue claim 14 is a two-part claim that includes a Markush genus of diseases that may be treated with the active ingredient of the present invention and a "normal format" method claim for particularly pointing out the method of administration of the

active ingredient. A Markush claim is generally considered to be somewhat atypical, within the general context of claim formats.

→ Claim scope change due to addition/deletion of terms: Markush claims vs. normal claims. In a typical, non-Markush claim, addition of claim terms ordinarily results in a narrowing of claim scope; but because of the language used to define the genus in a Markush claim, the addition of terms, i.e., the addition of members to the group in a Markush group ordinarily results in a broadening of claim scope. Similarly, amendment of a "normal" claim through removal or deletion of a claim term usually results in a broadening of the scope of the claim. In contrast, amendment of a Markush claim through removal or deletion of one or more members of its Markush group usually results in a narrowing of the scope of the claim. Important concept for recapture estoppel because the outcome of particular tests used in application of the recapture estoppel doctrine often depends on whether a certain claim has been broadened or narrowed by amendment, and because the case law often refers to such broadening or narrowing only in terms of adding or deleting claim terms without mentioning the type of claim. In the absence of mentioning the type of claim, it us usually assumed that a "normal" claim, rather than a "Markush" claim is at issue. Thus, in order to avoid drawing a wrong conclusion on the basis of wrongly evaluating claim scope changes, it is especially important to consider the specific nature of the Markush claim at issue here.

→ Claim 1 of the '833 patent is also directed to a method of treatment using the active ingredient of the present invention, and is set forth, as follows:

> 1. A method of treatment of a reversible obstructive airways disease comprising administering, by inhalation, to a patient suffering from, or susceptible to, such a condition the nebulised contents of an ampoule of carbon dioxide permeable plastics material filled with a unit dose of an aqueous pharmaceutical solution containing, as an active ingredient, from 0.1 to 5% w/v of 9-ethyl-6, -dihydro-4, 6-dioxo-10-propyl-4H-pyranol (3,2) quinoline-2, 8-dicarboxylic acid, or a pharmaceutically acceptable salt thereof, the solution having a pH of 3.5 to 6.0.

B. The Final Rejection Of Claims 14-19 Should Be Reversed Because No Admission Of Unpatentability Has Been Made Concerning The Subject Matter Of These Claims

→ The Federal Circuit distinguishes surrendered subject matter that triggers application of the recapture rule from surrendered subject matter does not, i.e., an exception to application of the rule. Not all subject matter that may have been claimed at one time during prosecution of the application but not found in the patent claim is "surrendered subject matter" for the purpose of the recapture estoppel doctrine. Specifically, the Federal Circuit has emphasized that ". . . the recapture rule does not apply in the absence of evidence that the applicant's amendment was 'an admission that the scope of that claim was not in fact patentable.'" *In re Clement,* 131 F.3d 1464, 1468-9, 45 USPQ2d 1161, 1164 (quoting *Seattle Box. Co. v. Indus. Crating & Packing, Inc.,* 731 F2d 818, 826, 221 USPQ568, 574).

→ To make this determination, one must ". . . look to the prosecution history for arguments and changes to the claims made in an effort to overcome a prior art rejection." *Clement, supra*, 131 F.3d at 1469, 45 USPQ2d at 1164, *citing Mentor,* 998 F.2d at 995-96, 27 USPQ2d at 1524-25; *Ball Corp., supra,* 729 F2d at 1436, 221 USPQ at 294-95.

→ "[T]he court may draw inferences from changes in claim scope when other reliable evidence of the patentee's intent is not available." *Clement, supra*, 131 F.3d at 1469, 45 USPQ2d at 1164 (*quoting, Ball,* supra, 729 F2d at 1436, 221 USPQ at 294).

→ When other reliable evidence of the patentee's intent is not available, the deliberate cancellation or amendment of ". . . a claim in an effort to overcome a reference strongly suggests that the applicant admits that the scope of the claim before the cancellation or amendment is unpatentable, *but it is not dispositive because other evidence in the prosecution history may indicate the contrary.*" (Emphasis added). *Clement, supra,* 131 F.3d at 1469, 45 USPQ2d at 1164.

→ **Evidence of intent not to abandon:**

→ The broadest prosecution claim – original claim 1

Claim 1 of the '520 application is the broadest method of treatment claim in the four-application series, is a Markush type claim and is reproduced below:

> 1. A method of treatment of a disease selected from the group comprising:
>
> conjunctivitis, keratitis, "allergic eyes," adenovirus infections, corneal homograft rejection, anterior uveitis,
>
> nasal polyps, vasomotor rhinitis, allergic manifestations of the nasopharynx,
>
> reversible obstructive airways disease,
>
> Crohn's disease, distal colitis and proctitis,
>
> which method comprises administration to a patient suffering from such a condition of a therapeutically effective amount of an aqueous solution containing, as active ingredient 9-ethyl-6, -dihydro-4, 6-dioxo-10-propyl-4H-pyranol (3,2) quinoline-2, 8-dicarboxylic acid, or a pharmaceutically acceptable salt thereof.

a. This broadest original application claim is directed to six types of eye of diseases, three types of nasal diseases, reversible obstructive airways disease and three types of colon diseases, all of which are described in the specification.

→ During the 7 years and 3 months of effort expended to obtain the '833 patent, the broadest method of treatment claim was amended and or replaced several times. During the original prosecution, twenty-two rejections of interest[1] were made to various versions of the broadest method of treatment claim. These rejections included twenty prior art rejections made under 35 U.S.C. §§102, 103, and two rejections made under 35 U.S.C. §112.

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[1] Several obviousness type double patenting rejections were made during the original prosecution. However, these rejections are not relevant to the recapture estoppel issue presented, and are therefore not further mentioned.

→ Of the twenty prior art rejections only one related to treatment of eye disease; the rest related to treatment of reversible obstructive airways disease and/or Crohn's disease.

Regarding the prosecution of the broadest method of treatment claim in each of the applications in the original prosecution, all prior art rejections, except one, were rejections to a generic Markush claim on the ground that the species "reversible obstructive airways disease" was anticipated or obvious. No admission was made that any claimed eye disease treatment subject matter was, in fact, not patentable. The final rejection has not alleged or pointed to any evidence in the record that establishes, suggests or supports a conclusion of abandonment in fact. The first exception to application of the recapture rule to reissue application claims 14-19 is therefore established.

→ The single prior art rejection of a claim to treatment of an "eye disease" was a rejection made to claim 1 in the '020 application on 03/08/90 on the ground that claim 1 was obvious from the Fisons '722 publication. However, in the reply to that rejection applicants pointed out that the Fisons publication was directed to an eye disease different from any eye disease claimed. Specifically, applicants argued that ". . . the newly cited Japanese Fisons patent '722 relates to the treatment of certain eye disorders associated with diabetes . . .." In this regard, Fisons '722 states:

> ". . . we surprisingly discovered that these compounds could be used for the preventive as well as therapeutic treatment of cataracts, retinopathy, neuropathy, angiopathy, and nephropathy in patients with diabetes mellitus."

Fisons '722 at 4, ¶4. This is a statement that applicants did **not** consider any amendment to the claims necessary in regard to treatment of eye diseases listed in the claims for any reason of patentability in light of the Fisons '722 publication[2]. It is a denial of unpatentability; not an admission of unpatentability.

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[22]. In addition, the compound disclosed in Fisons '722 to be the active ingredient is different than the active ingredient in rejected claim 1.

→ Also, the specification does not provide support for any eye disease associated with diabetes mellitus; and Fisons '722 does not to disclose the active ingredient of the present invention. Thus, the rejection was not credible.

C. The Final Rejection Of Claims 14-19 Should Be Reversed Because The Scope Of The Broadest Independent Claim 14 Has Been Materially Narrowed In Comparison To The Scope Of The Corresponding Claim In The Original Prosecution

→ The a second exception to the recapture estoppel doctrine is established when the reissue claims are materially narrowed in an overlooked aspect of the claims. *Pannu v. Storz Instrument, Inc., supra*, 258 F.3d 1366, 59 USPQ2d 1597; *Hester Indus., Inc. v. Stein, Inc., supra*, 142 F.3d at 1482-83, 46 USPQ2d at 1641. In Hester, the Federal Circuit explained this exception as follows:

> . . . this principle, in appropriate cases, may operate to overcome the recapture rule when the reissue claims are materially narrower in other overlooked aspects of the invention. The purpose of this exception to the recapture rule is to allow the patentee to obtain through reissue a scope of protection to which he is rightfully entitled for such overlooked aspects.

→ Original application claim 1 listed all six of the eye diseases described in the specification, three nasal diseases and three colon diseases. The original prosecution focused on the reversible obstructive airways disease, and overlooked this other subject matter, in original claim 1 and its variations.

→ In sharp contrast, reissue application claim 14 lists only 4 of the 6 eye diseases, and none of the other diseases. [Because these claims are Markush claims, the listing of 4 eye diseases in the later reissue application claim 14, compared to the listing of 6 eye diseases, and the other diseases in the earlier prosecution claims represents a narrowing of scope (from 6 eye diseases to only 4 eye diseases, and from 4 types of diseases to only 1 type of disease that may be treated with the active ingredient of the present invention)]. Thus this eye disease subject matter was overlooked during the original prosecution. Although some twenty prior art rejections made, only one made any reference to eye disease, and that one was so weak as to be not credible. Indeed, that rejection was

withdrawn in response to the subsequent reply made by applicants, and never again asserted during the original prosecution.

D. The Final Rejection Of Claims 10 and 15 Should Be Reversed Because The Scope Of The Claims Is Materially Narrower Than The Scope Of The Corresponding Claim In The Original Prosecution

Coverage of several sub-genus claims narrowed to 1 sub-genus (conjunctivitis).

E. The Final Rejection Of Claims 13 and 16 Should Be Reversed Because The Scope Of The Claims Is Materially Narrower Than The Scope Of The Corresponding Claim In The Original Prosecution

Coverage of several sub-genus claims narrowed to 1 species (seasonal allergic conjunctivitis).

F. The Final Rejection Of Claims 12 and 17 Should Be Reversed Because The Scope Of The Claims Is Materially Narrower Than The Scope Of The Corresponding Claim In The Original Prosecution

Coverage of several sub-genus claims narrowed to 1 species (allergic conjunctivitis).

G. The Final Rejection Of Claims 11 and 18 Should Be Reversed Because The Scope Of The Claims Is Materially Narrower Than The Scope Of The Corresponding Claim In The Original Prosecution

Coverage of several sub-genus claims narrowed to 1 species (vernal conjunctivitis)

APPENDIX A

CLAIMS ON APPEAL

10. A method of controlling the symptoms of conjunctivitis comprising administering to the eye of a patient having conjunctivitis an effective amount of nedocromil sodium in an ophthalmically acceptable formulation.

11. The method of claim 10, wherein the conjunctivitis is vernal conjunctivitis.

12. The method of claim 10, wherein the conjunctivitis is allergic conjunctivitis.

13. The method of claim 10, wherein the conjunctivitis is seasonal allergic conjunctivitis.

14. A method of treatment of a disease selected from the group consisting of conjunctivitis, keratitis, allergic eyes, and anterior uveitis, which method comprises administering to the eye an effective amount of an ophthalmically acceptable aqueous pharmaceutical solution containing the active ingredient 9-thyl-6, -dihydro-4, 6-dioxo-10-propyl-4H-pyrano(3,2)quinoline-2, 8-dicarboxylic acid, or a pharmaceutically acceptable salt thereof.

15. The method of claim 14, wherein the disease is conjunctivitis.

16. The method of claim 15, wherein the disease is seasonal allergic conjunctivitis.

17. The method of claim 15, wherein the disease is allergic conjunctivitis.

18. The method of claim 15, wherein the disease is vernal conjunctivitis.

19. The method of claims 14, 15, 16, 17 or 18, wherein said active ingredient is nedocromil sodium.

Appeal Brief
Application No. 09/654,738

PATENT
Attorney Ref 21407.0001

#25
4/8/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Title	:	**Pharmaceutical Compositions**
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Examiner	:	Robert M. Joynes
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APPELLANTS' BRIEF TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

CERTIFICATE OF MAILING (37 C.F.R. § 1.8(a))

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Mary Helen Lopez

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APPELLANTS' BRIEF TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

I. INTRODUCTION

A. Nature of the Appeal

This is an appeal from the June 28, 2002, final rejection of claims 10-19 in application 08/916,578 ("the '578 application"). Finally rejected claims 10-19 are reproduced in Appendix 1. The '578 application is for reissue of U.S. Patent No. 5,443,833 ("the '833 patent") issued on August 22, 1995, and entitled "Pharmaceutical Compositions". A copy of the '833 patent is submitted as Appendix 2.[1] The '578 reissue application was filed on August 22, 1997, and thus the scope of its claims may be enlarged in comparison to the scope of the claims in the '833 patent, as permitted under 35 U.S.C. § 251 (1952). The sole ground of rejection is that the recapture estoppel rule bars patent protection to the claims now on appeal.

The nedocromil sodium ophthalmic solution of finally rejected claims 10-13 has exhibited substantial commercial success. Allergan has received FDA approval to market its Alocril® brand nedocromil sodium ophthalmic solution for treatment of itching associated with allergic conjunctivitis. In 2002, the Alocril® ophthalmic solution enjoyed about $20,000,000 in sales.

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[1] For convenience, citation to the specification will be made to the specification as formatted in the '833 patent, by column and line number. Thus, 1:55-2:3 refers to column 1, line 55 through column 2, line 3 of the '833 patent. Appendix 2.

B. Summary of Argument

Except for the unusual circumstances of having Markush claims at issue and of having a lengthy, convoluted prosecution history in the record on appeal, this is a straightforward appeal of a recapture estoppel rule final rejection that is reversible error for three independent reasons.

First, in regard to application of the recapture rule to "Markush-type grouping" claims it is well settled ". . . that claims of a scope narrower than claims cancelled from the original application may be obtained by reissue." *Application of Wadlinger*, 496 F.2d 1200, 181 USPQ 826 (CCPA 1974). Here the broadest claim cancelled from the original application was directed to treatment of twenty-four eye, nasal, colon and airway diseases,[2] but the broadest reissue application claim has a much narrower scope, i.e., treatment of only fourteen eye diseases. *Wadlinger* requires reversal of the final rejection.

Second, the mere fact of cancellation of a claim prosecuted during an effort to obtain the original patent is not the only fact relevant to application of the recapture estoppel rule, as appears to be the position taken in the final rejection, but rather is the starting point. Controlling Federal Circuit authority requires that all of the evidence from the prosecution history be examined to determine whether, as a matter of fact, the applicant admitted the unpatentability of the subject matter of

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[2] The terms "disease(s)," "condition(s)" and "disorder(s)" are used synonymously in the '833 patent. *See, e.g.*, 1:36 ("disorders"); 1:40 ("condition"); and 1:47 ("disease"). Appendix 2. For convenience and consistency, this brief will use the term "disease(s)", unless quoting language that uses another synonym.

the cancelled claim during the original prosecution. It is well settled that in the absence of an applicant's admission of unpatentability, application of the recapture rule is reversible error. *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir.1997). In the record before the Board of Patent Appeals and Interferences (the "Board") in this appeal, not only is there no evidence of admission of unpatentability of the appealed eye disease treatment subject matter, but also there is affirmative, reliable evidence that these applicants denied unpatentability of the eye disease treatment subject matter over the cited prior art and expressly stated their continued belief that this subject matter was patentable. The final rejection should be reversed for this reason alone.

Third, when a reissue claim is narrower than an original application claim in an aspect germane to a prior art rejection, and broader in an aspect unrelated to the rejection, the recapture rule does not bar the claim. *Clement, supra*, 131 F.3d at 1470, 45 USPQ2d at 1165. In the present appeal all claims have two aspects: (1) certain treatable diseases; and (2) administration of the active ingredient. In the present appeal, all reissue claims are narrower in the treatable diseases aspect (fourteen diseases) than was the original prosecution claim (twenty-four eye, nasal, colon and airway diseases). The reissue claims are broader in the administration aspect because each requires only that the administration of the active ingredient be by an ophthalmically acceptable aqueous solution, but the cancelled claim in the original application had seven additional requirements to the administration aspect. Under this third rule the final rejection should also be reversed.

C. The Prosecution History Includes Four Applications and Two Reissue Applications

Four applications were prosecuted in obtaining the '833 patent, including application 82,804 ("the '804 application"), the application from which the '833 patent issued, its parent application 742,574 ("the '574 application"), its grandparent application 410,020 ("the '020 application") and its great-grandparent application 133,520 ("the '520 application" or "the original application").

The '578 reissue application was filed on August 22, 1997, and included claims 1-3 as issued in the '833 patent, and new claims 4-13 directed to treatment of and controlling various eye diseases using an aqueous solution of the active ingredient. New claim 4 is independent and is directed to a method of treatment of certain eye diseases through administration of the active ingredient. New claim 10 is directed to a method of controlling the symptoms of conjunctivitis through administration of the active ingredient.

Following several amendments in the reissue applications, new claims 4-13 became claims 14-19 directed to this eye disease subject matter. Claims 14-19 were finally rejected on June 28, 2002, ". . . as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based." Final Rejection dated June 28, 2002, at 2-3. Appendix 3. A summary of the relevant prosecution history of the applications and the reissue applications is provided in Appendix 3.

II. REAL PARTIES IN INTEREST

The real parties in interest are the assignee of the subject application, Fisons plc, Ipswich, England and its exclusive licensee, Allergan, Inc. ("Allergan"), Irvine, California.

III. RELATED APPEALS AND INTERFERENCES

There is no related appeal or interference.

IV. STATUS OF CLAIMS

The status of all claims is as follows.

Claims 1-3 and 10-19 are pending.

Claims 1-3 have been allowed.

Claims 4-9 have been cancelled.

Claims 10-19 have been finally rejected.

V. STATUS OF AMENDMENTS

No amendment has been filed subsequent to the final rejection.

VI. SUMMARY OF INVENTION

The invention of the claims on appeal is a method of treatment of a variety of diseases of the human eye with an effective amount of nedocromil sodium administered in an ophthalmically acceptable formulation. The claims on appeal are limited to fourteen eye diseases of

the twenty-four eye, nasal, colon and airway diseases described in the '833 patent.

Finally rejected independent claim 14 is the broadest reissue claim, and covers fourteen eye diseases. Finally rejected independent claim 10 is limited to conjunctivitis (inflammatory disorder of the conjunctiva commonly characterized by photophobia and irritation). Appendix 1; Appendix 2, 1:55-57. Claims 11-13 depend from claim 10 and are directed to three specific types of conjunctivitis (vernal conjunctivitis, allergic conjunctivitis and seasonal allergic conjunctivitis). Appendix 1; Appendix 2, 1:57-64.

The '833 patent describes a method of treatment of twenty-four diseases, categorized into a Markush-type group consisting of a sub-group of human eye diseases, a sub-group of human nasal diseases, human reversible obstructive airway disease and a sub-group of human colon diseases. The eye disease sub-group is further categorized into six sub-sub-groups; the nasal disease sub-group is further categorized into three sub-sub-groups; and the colon disease sub-group is further categorized into three sub-sub-groups. The treatment is by application of a therapeutically effective amount of an aqueous solution of nedocromil or a pharmaceutically acceptable salt thereof. The preferred active ingredient is the disodium salt, referred to as nedocromil sodium[3] in the '833 patent. These diseases are described at 1:34-2:5, Appendix 2, and for convenience, all are categorized in Appendix 4.

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[3] Nedocromil sodium is the common name for the sodium salt of 9-thyl-6, -dihydro-4, 6-dioxo-10-propyl-4H-pyrano (3,2)quinoline-2, 8-dicarboxylic acid.

Various details of the administration of the active ingredient aspect of the claims are described in the '833 patent. None of these details of the invention is relevant to the issues on appeal, except as discussed, *infra*, in regard to comparison of the scope of this aspect of the reissue claims to the scope of this aspect of the cancelled claim 18.

VII. ISSUE PRESENTED ON APPEAL

The issue presented is whether the final rejection of claims 10-19 under the recapture estoppel rule is reversible error.

VIII. GROUPING OF CLAIMS ON APPEAL

Claims 10-19 do not stand or fall together. Rather, the appealed claims should be placed in several groups and each group considered separately, for several reasons.

Claims 10-19 should be considered as a separate group for the reasons that (1) these claims are of a narrower scope than claims cancelled from the original application and/or (2) applicants made no admission of unpatentability of the subject matter of these claims during prosecution that lead to issuance of the '833 patent.

Claims 14-19 should be considered as a separate group because the broadest claim in this group, claim 14, is substantially narrower in scope in the treatable diseases aspect of that claim than the corresponding, broadest claim 18 cancelled during prosecution that lead to the original '833 patent, but is broader in the administration aspect of that claim.

Claims 10 and 15 should be considered as a separate group because these claims are further limited in the treatable disease aspect so as to be even narrower in scope than that of reissue claim 14.

Each pair of claims 13, 16; 12, 17; and 11, 18, should be treated as a separate group because each pair is limited in the treatable disease aspect to a scope that is even narrower than that of claims 10 and 15.

IX. ARGUMENT

A. Controlling Authority Specific To Application Of The Recapture Rule To Markush-Type Claims Mandates Reversal

This appeal is somewhat unusual in that appellants found no case authority that applied the recapture estoppel rule to a fact pattern in which classic Markush claims were at issue. However, the *Wadlinger* fact pattern and the Markush-type claim language are remarkably similar to those here. The claims at issue in *Wadlinger* were referred to as a "Markush-type grouping" because they used Markush language that was different than "classic" Markush language by a single word. *Id.*, 496 F.2d at 1205, 181 USPQ at 830. A copy of *Wadlinger* is submitted as Appendix 5.

Wadlinger concerned synthetic zeolites and processes using them as catalysts. There the claims used the "Markush-type" phrase ". . . with a fluid medium containing ions *selected from the class consisting of* hydrogen ions and ammonium ions" rather than the classic phrase "selected from the group consisting of." [Emphasis added.] *Id.*, 496 F.2d at 1201, 181 USPQ at 827. However, in *Wadlinger* the use of the word

"class" to define a Markush group rather than the word "group" as is used in the classic Markush definition was of no significance to application of the recapture estoppel rule.

In *Wadlinger*, the Board affirmed the examiner's application of the recapture estoppel rule to bar reissue application claims for the reason that "...appellants deliberately cancelled claims of similar scope in the prosecution of their original patent." *Id.*, 496 F.2d at 1204, 181 USPQ at 829. The Court reversed the decision of the Board, holding that the rejected claims were narrower in scope than the cancelled claims. The Court opined that the determination centered on whether the rejected claims were narrower or broader in scope than the cancelled claims. *Id.*, 496 F.2d at 1205-06, 181 USPQ at 830-31.

The uncontroverted evidence of record in this appeal establishes that the broadest rejected reissue claim is narrower (treatment of fourteen eye diseases) than the broadest cancelled claim (treatment of twenty-four eye, nasal, colon and airway diseases). Similarly, the record also shows that rejected reissue conjunctivitis claim 10 (treatment of seven types of conjunctivitis) and its dependent claims 11-13 (treatment of three types of conjunctivitis) are narrower than the cancelled claims. Accordingly, under *Wadlinger*, the Board must reverse the final rejection of claims 10-19.

B. The Three-Step Process Used In General Application Of The Recapture Estoppel Rule Also Mandates Reversal

Generally stated, the recapture estoppel rule prevents a patentee from regaining through reissue subject matter surrendered in an effort to obtain allowance of original patent claims. Under recent Federal Circuit recapture rule opinions, the Court has said that claims that are "broader than the original patent claims in a manner *directly pertinent* to the subject matter surrendered during prosecution" are impermissible. [Emphasis added.] *Clement, supra*, 131 F.3d at 1468, 45 USPQ2d at 1163; *Ball Corp. v. United States*, 729 F.2d 1429, 221 USPQ 289 (Fed. Cir. 1984). A copy of *Clement* is submitted as Appendix 6, and a copy of *Ball* is submitted as Appendix 7.

In the general application of the recapture estoppel rule, a three-step process is used. *Pannu v. Storz Instrument, Inc.*, 258 F.3d 1366, 1371, 59 USPQ2d 1597, 1600 (Fed. Cir. 2001); *Clement, supra* (three steps used in application of the rule, but not expressly referred to as a "three-step process"). A copy of *Pannu* is submitted as Appendix 8.

The first step is to "determine whether and in what 'aspect' the reissue claims are broader than the patent claims." *Pannu, supra*, 258 F.3d at 1371, 59 USPQ2d at 1600 (*citing Clement*, 131 F.3d at 1468, 45 USPQ2d at 1164). If the reissue claims are broader than the patent claims, the analysis proceeds to the second step. In this regard the reissue claims are broader in some aspects than the patent claims, so the analysis proceeds to the second step.

According to the Federal Circuit, "[t]he second step is to determine whether the broader aspects of the reissued claim related to surrendered subject matter." *Id.* If the broader aspects of the reissue claim relate to surrendered subject matter, then the analysis proceeds to the third step. In this regard appellants will show that the broader aspect of the reissue claims does not relate to surrendered subject matter, and that the Board need not consider the third step.

Finally, according to the Federal Circuit, the third step is to determine ". . . whether the reissued claims were materially narrowed in other respects to avoid the recapture rule." *Id.*, citing *Hester Indus., Inc. v. Stein, Inc.*, 142 F.3d 1472, 1482-83, 46 USPQ2d 1641, 1649-50 (Fed. Cir. 1998); and *Clement*, 131 F.3d at 1470, 45 USPQ2d at 1165. A copy of *Hester* is submitted as Appendix 9. In this regard, appellants will show that the reissue claims were materially narrowed in other respects to avoid the recapture rule.

C. Step 1: Comparison Of The Scope Of The Broadest Reissue Claim To The Scope Of The Broadest '833 Patent Claim – Here The Reissue Claim Is Broader

The first step in the three-step application of the recapture estoppel rule is to determine whether and in what aspect the reissue claims are broader than the patent claims. In this appeal the comparison is between independent claim 14 of the '578 reissue application and

independent claim 1 of the '833 patent.[4] As will be shown, reissue claim 14 is broader than patent claim 1.

1. Reissue Claim 14: A Two-Part Markush Claim

Claim 14 of the '578 reissue application is set forth, as follows:

> 14. A method of treatment of a disease selected from the group consisting of conjunctivitis, keratitis, allergic eyes, and anterior uveitis, which method comprises administering to the eye an effective amount of an ophthalmically acceptable aqueous pharmaceutical solution containing the active ingredient 9-ethyl-6, -dihydro-4, 6-dioxo-10-propyl-4H-pyranol (3,2) quinoline-2, 8-dicarboxylic acid, or a pharmaceutically acceptable salt thereof.

Amendment mailed July 9, 2001 at 1; Appendix 1; Appendix 10.[5]

Reissue claim 14 is a two-part Markush[6] claim that includes in its first part or aspect, a Markush group whose four members are four of the

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[4] For the purpose of the step 1 claim scope comparison, only reissue application claim 14 need be compared to patent claim 1. In this sense only, reissue application claim 14 is representative of reissue application claims 10-13 and 15-19 because it is the broadest of, and encompasses these claims. Patent claim 1 is representative of claims 2-3 because they depend from patent claim 1.

[5] Appendix 10 provides the prosecution amendment history of the original and amended broadest method claims that lead to the '833 patent and of the claims in the reissue application.

[6] Reissue application claim 14 is a Markush claim because it recites members of a group (the Markush group) in the form ". . . selected from the group consisting of A, B . . .." *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925); Manual Of Patent Examining Procedure ("MPEP") *§§ 803.02, 2173.05(h), 2173.05(o)*. When the Markush group is found in a claim reciting a process, it is sufficient if the members of the group are disclosed in the specification to

six sub- sub-groups of diseases disclosed in the specification as treatable with the pharmaceutical solution of the present invention; and in its second part or aspect a "normal format" method of administration of the pharmaceutical solution.

2. Original '833 Patent Claim 1

Claim 1 of the '833 patent is:

> 1. A method of treatment of a reversible obstructive airways disease comprising administering, by inhalation, to a patient suffering from, or susceptible to, such a condition the nebulised contents of an ampoule of carbon dioxide permeable plastics material filled with a unit dose of an aqueous pharmaceutical solution containing, as an active ingredient, from 0.1 to 5% w/v of 9-ethyl-6, -dihydro-4, 6-dioxo-10-propyl-4H-pyranol (3,2) quinoline-2, 8-dicarboxylic acid, or a pharmaceutically acceptable salt thereof, the solution having a pH of 3.5 to 6.0.

'833 patent, 8: 18-28, Appendix 2.

Claim 1 of the '833 patent is also directed to a method of treatment using an aqueous solution of the active ingredient of the present invention; however, the patent claim is not a Markush claim, and does not concern treatment of any eye disease. This claim is directed to

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possess at least one property in common which is mainly responsible for their function in the claimed relationship. *Id., § 2173.05(i).* In regard to reissue application claim 14, the Markush group includes four members (of eye diseases). These diseases are not only described in the specification, but also specific definitions for some of them are provided at 1:55-2:3, Appendix 2. These four types of eye diseases have in common their susceptibility to treatment with an aqueous solution of the active ingredient of the present invention.

treatment of only reversible obstructive airways disease (disease (20) in Appendix 4). While the administration of the active ingredient is also by aqueous solution, the claimed administration of the active ingredient is different from reissue application claim 14 in numerous respects, as discussed below.

3. Reissue Application Claim 14 Is Broader Than Patent Claim 1 In Nine Aspects

In the sense that reissue claim 14 covers nine aspects that are not covered by patent claim 1, reissue claim 14 is broader than patent claim 1. These nine aspects are detailed and summarized in Appendix 11. Specifically, the reissue claim covers treatment of four types of eye diseases, but the patent claim covers treatment of (1) no type of eye disease. Regarding administration of the active ingredient, the reissue application claim covers administration to the eye, but the patent claim (2) does not cover any administration to the eye. Rather, the patent claim is limited to inhalation. Also, in the patent claim administration of active ingredient is limited to (3) a unit dose of a (4) nebulised solution (5) in an ampoule that is (6) made of plastic and is (7) carbon dioxide permeable, and the active ingredient is (8) from 0.1 to 5% w/v and has (9) a pH of 3.5 to 6.0. In contrast, reissue application claim 14 has no limitation regarding (3) - (9).

Thus, the reissue application claims are broader than the patent claims in nine aspects.

D. Step 2: Whether The Broader Aspects Of Reissue Claim 14 Relate To Surrendered Subject Matter – Here They Do Not

Step 2 is ". . . to determine whether the broader aspects of the reissued claim related to surrendered subject matter." *Pannu, supra,* 258 F.3d at 1371, 59 USPQ2d at 1600. If the broader aspects relate to surrendered subject matter, then the application of the recapture estoppel rule proceeds to step 3. However, if the broader aspects do not relate to surrendered subject matter, then the recapture rule does not apply. The Federal Circuit has developed specific rules to determine whether "particular subject matter" has been surrendered in the context of step 2 of a general recapture estoppel analysis. Specifically, the Court requires that:

> . . . To determine whether an applicant surrendered *particular subject matter,* we look to the prosecution history for arguments and changes to the claims made in an effort to overcome a prior art rejection. [citing *Mentor Corp. v. Coloplast, Inc.,*[7] 998 F.2d 992, 994, 27 USPQ2d 1521, 1524 (Fed. Cir. 1993); *Ball Corp. v. United States,* 729 F.2d 1429, 1436, 221 USPQ 289, 294-95 (Fed. Cir. 1984)].
>
> * * *
>
> Although *the recapture rule does not apply in the absence of evidence that the applicant's amendment was 'an admission that the scope of that claim was not in fact patentable,' Seattle Box Co. v. Industrial Crating & Packing, Inc.*[8], 731 F.2d 818, 826, 221 USPQ 568, 574 (Fed. Cir. 1984), 'the court may draw inferences from changes in claim scope when other reliable evidence of the patentee's intent is not

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[7] A copy of *Mentor* is submitted as Appendix 12.

[8] A copy of *Seattle Box* is submitted as Appendix 13.

> available,' *Ball*, 729 F.2d at 1436, 221 USPQ at 294. *Deliberately canceling or amending a claim in an effort to overcome a reference* strongly suggests that the applicant admits that the scope of the claim before the cancellation is unpatentable, but it *is not dispositive because other evidence in the prosecution history may indicate the contrary.* ** *See Mentor*, 998 F.2d at 995-96, 27 USPQ2d at 1524-25; *Ball*, 729 F.2d at 1438, 221 USPQ at 296; *Seattle Box Co.*, 731 F.2d at 826, 221 USPQ at 574 (declining to apply the recapture rule in the absence of evidence that the applicant's 'amendment . . . was in any sense an admission that the scope of [the] claim was not patentable').

Clement, supra, 131 F.3d at 1469, 45 USPQ2d at 1164. [Emphasis added.]

As emphasized by the Federal Circuit, the recapture rule does not apply in the absence of evidence that the patentee's claim amendment was an admission that the scope of the claim before amendment was not, in fact, patentable in regard to "particular subject matter." *Id.* Here the "particular subject matter" is the treatment of certain eye conditions by a pharmaceutical solution of the active ingredient.

In the final rejection the examiner has cited no evidence of any admission of unpatentability, except for the bare fact of cancellation of the broader original prosecution claim. However, under *Clement*, the cancellation merely raises a presumption, and is the starting point of the analysis; not the ending point. Also, the record in this appeal contains a wealth of "reliable evidence of the patentee's intent" not to abandon the particular subject matter. This reliable evidence demonstrates that the applicants not only did not admit unpatentability of the original prosecution claim, but that they affirmatively denied such an admission

and stated their belief in the patentability of that subject matter, as detailed below.

1. The Broadest Original Prosecution Claim Included Eye Treatment Subject Matter Not Included In Patent Claim 1

In light of the above law and the fact that the effort to obtain allowance of patent claims began with the original '520 application, the second step in applying the recapture estoppel rule in this case requires review of the entire prosecution history of all four applications in the series. Specifically, the second step in this case involves identification of the broadest method of treatment claim in those four applications, identification of subject matter covered by the broadest prosecution method claim, comparison of that subject matter to the patent claim and determination of what, if any "particular subject matter" was "surrendered" for the purpose of application of the recapture estoppel rule.

Claim 1 of the '520 application, reproduced below, is a Markush claim and is the broadest method of treatment claim in the four-application series:

> 1. A method of treatment of a disease selected from the group comprising:
>
> conjunctivitis, keratitis, "allergic eyes," adenovirus infections, corneal homograft rejection, anterior uveitis,
>
> nasal polyps, vasomotor rhinitis, allergic manifestations of the nasopharynx,
>
> reversible obstructive airways disease,

Crohn's disease, distal colitis and proctitis,

which method comprises administration to a patient suffering from such a condition of a therapeutically effective amount of an aqueous solution containing, as active ingredient 9-ethyl-6, -dihydro-4, 6-dioxo-10-propyl-4H-pyranol (3,2) quinoline-2, 8-dicarboxylic acid, or a pharmaceutically acceptable salt thereof.

'520 application; Appendix 10.

This broadest original application claim is directed to twenty-four eye, nasal, colon and reversible obstructive airways diseases. Regarding the administration aspect of the claim, the claim has only two limitations: a pharmaceutical solution of the active ingredient is administered (1) in an aqueous solution, and (2) in a therapeutically effective amount.

2. The Eye Treatment Subject Matter That The Examiner Erroneously Concluded Had Been Surrendered

To identify the subject matter that, presumptively, has been surrendered during prosecution, the scope of the broadest application claim, '520 application claim 1 together with its various amendments, cancellations and replacements must be considered and compared to the scope of patent claim 1. During the 7 years and 3 months of effort expended to obtain the '833 patent, the broadest method of treatment claim was amended and/or cancelled and replaced several times. A detailed history of each and every change to the broadest method of treatment claim in the original prosecution is found in Appendix 10.

During the original prosecution, twenty-five rejections[9] relevant or otherwise of interest to the recapture estoppel rule issue on appeal were made to various versions of the broadest method of treatment claim. These rejections included a series of twenty-three prior art rejections made under 35 U.S.C. §§ 102 and/or 103 and two rejections made under 35 U.S.C. § 112. Of the twenty-three prior art rejections, only one related to rejection of a method of treatment of eye disease; the rest related to compositions including the active ingredient or to the treatment of reversible obstructive airways disease and/or Crohn's disease. A summary of these rejections is provided in Appendix 14.

Therefore, of all of the claims in that series, the one that is the basis for the step 2 analysis of the recapture rule is claim 18, just prior to cancellation. Application claim 18 was cancelled by an amendment that was received in the Patent Office Mail Room on February 16, 1995. On that date, claim 18 had the following terms:

> 18. A method of treatment of a disease selected from the group consisting of conjunctivitis, keratitis, "allergic eyes," adenovirus infections, corneal homograft rejection, anterior uveitis, nasal polyps, vasomotor rhinitis, allergic manifestations of the nasopharynx, reversible obstructive airways disease, Crohn's disease, distal colitis and proctitis, which method comprises administering to a patient suffering from such a condition the contents of an ampoule of carbon dioxide permeable plastics material filled with a unit dose of an aqueous pharmaceutical solution containing, as active

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[9] Several obviousness-type double patenting rejections were made during the original prosecution. However, these rejections are not relevant to the recapture estoppel issue presented, and are therefore neither counted nor further mentioned.

> ingredient, 9-ethyl-6, 9-dihydro-4, 6-dioxo-10-propyl-4H-pyrano (3, 2-g) quinoline-2, 8-dicarboxylic acid or a pharmaceutically acceptable salt thereof, and sealed, the solution having a pH of 3.5 to 6.0 as defined in claim 7.

Appendix 10. This cancelled claim 18 was replaced with new claims 23-25, which, without amendment, became claims 1-3 of the '833 patent. Appendix 10. Cancelled claim 18 was a two-part Markush claim, similar to the broadest form of original application claim 1.

The treatable disease aspect of cancelled claim 18 recited the same Markush group as did the original application claim 1, i.e., a group that included all six of the eye disease sub-sub groups, all three of the nasal disease sub-groups, all three of the colon disease sub-groups and obstructive airway disease.

The active ingredient administration aspect of cancelled claim 18 recited the pharmaceutical solution, as did original application claim 1. However, since the filing of original application claim 1, a number of narrowing amendments had been made to this aspect of claim 1 and its replacement, claim 18. Whereas the broadest reissue claim, claim 14, requires merely that the active ingredient be administered (1) in an effective amount (2) that was ophthalmically acceptable, cancelled claim 18 had seven additional requirements: that the active ingredient to be administered (1) in an ampoule (2) of carbon dioxide permeable (3) plastics material that was (4) sealed and (5) filled with a unit dose of an aqueous solution of the active ingredient (6) that was pharmaceutically acceptable and had (7) a pH of 3.5 to 6.0.

Because original claim 1 and its replacement, cancelled claim 18 cover treatment of the same eye disease, nasal disease and colon disease subject matter, but patent claim 1 has no coverage of any of these three types of disease subject matter, it appears that the examiner erroneously concluded that the following subject matter had been surrendered:

a. treatment of all six sub-sub groups of eye diseases;

b. treatment of all three sub-groups of nasal diseases;

c. treatment of all three sub-groups of colon diseases; and

d. all types of administration of the active ingredient permitted by original claim 1, i.e., all those for which support is found in the specification, except for the specific administration covered by patent claim 1.

Because all of the reissue claims are directed to one or more of the six sub- sub- groups of eye diseases, the examiner apparently concluded that this subject matter necessarily had been surrendered by cancellation of claim 18.

3. The Evidence In The Prosecution History Record on Appeal Is Reliable, Establishes That No Eye Condition Treatment Was Abandoned And Establishes That The Applicants' Intent Was To Patent The Eye Disease Subject Matter

All prior art rejections to the broadest method claim and its variations, except one, were rejections on the ground that the "reversible obstructive airways disease" and/or Crohn's disease subject was anticipated, or obvious and therefore rendered the entire Markush group anticipated or obvious. However, no admission was made by applicants

that any eye disease treatment subject matter was, in fact, not patentable. Also, other evidence in the prosecution history establishes that applicants did not surrender any eye disease subject matter but rather maintained their position that the eye disease subject matter was patentable throughout the prosecution. Regarding the prosecution of the broadest method of treatment claim in each of the applications in the original prosecution, those claims are reproduced in Appendix 10, and the corresponding rejections and applicants' replies are summarized in Appendix 14.

a. The Rejection Based On Eye Disease Treatment Prior Art

The single prior art rejection of a claim to a method of treatment of an "eye disease" was a rejection made to claim 1 in the '020 application in an Office Action dated March 8, 1990 (Rejection 13 in Appendix 14) on the ground that claim 1 was obvious from prior art referred to as the Fisons '722 publication. That rejection is reproduced below:

> Claims 1-17 are rejected under 35 U.S.C. 103 as being unpatentable over Fisons '722.
>
> Fisons '722 teaches the claimed compound in an eye treatment preparation. The treatment as taught by Fisons appears to anticipate the present claims. Accordingly, the burden of proof is upon applicant(s) to show that the instantly claimed subject matter is different from and unobvious over that taught by this reference. See *In re Brown*, 173 U.S.P.Q. 685, 688; *In re Best*, 195 U.S.P.Q. 430 and *In re Marosi*, 218 U.S.P.Q. 289, 293. In the event that applicant shows his composition to differ from that taught by Fisons, it would have been obvious to one of ordinary skill in the detergent art to combine the ingredients of the

> composition as taught by Fisons in optimal proportions since the broad teachings of Fisons encompass these proportions.

A copy of the Fisons '722 publication is submitted as Appendix 15.

b. The Reply To The Eye Disease Prior Art Rejection

In reply to the eye disease prior act rejection applicants expressly pointed out that the Fisons '722 publication was directed to treatment of eye diseases different from any eye disease claimed and implied, through submission of a complete, translated copy of the Japanese publication that the treatment was by use of compounds different than any claimed.

Specifically, applicants argued:

> The newly-cited Japanese Fisons patent '722 relates to the treatment of certain eye disorders associated with diabetes and thus would not suggest the method now claimed to one skilled in the art. Enclosed herewith is a copy of an English text corresponding to Fisons '722.

In this regard, Fisons '722 states:

> . . . we surprisingly discovered that these compounds could be used for the preventive as well as therapeutic treatment of cataracts, retinopathy, neuropathy, angiopathy, and nephropathy in patients with diabetes mellitus.

Fisons '722 at 4, ¶ 2. Appendix 15. None of these diseases are diseases described in the '833 patent specification.

Just as importantly, the compounds disclosed in Fisons '722 are different from those in the present appeal. Fisons '722, in pertinent part, provides:

> The compounds used as the active components of this invention are:
>
> 4,6-dioxo-5,10-dimethyl-4H,6H-benzo[3,2-g]dithiopyran-2,8-dicarboxylic acid,
>
> 4-[5-(2-hydroxypropyloxy)-4-oxo-4H-1-benzopyran-2-yl]benzoic acid,
>
> 6,7,8,9-tertrahdro-4-oxo-10-(2-hydroxypropyl)-4H-naphtho[2,3-b]pyran-2-carboxylic acid,
>
> 6,7,8,9-tetrahydro-10-(2,3-dihydroxypropyl-l-yl)-4-oxo-4H-naphtho[2,3-b]pyran-2-carboxylic acid,
>
> 7,8,9,10-tetrahydro-5-hydroxy-4-oxo-6-propyl-4H-naptho[1,2-b]-pyran-2-carboxylic acid, and their pharmacologically acceptable salts such as sodium salts.

Fisons '722, Appendix 15 at 8. None of these Fisons '722 compounds is the compound of the active ingredient of appellants' claims.

c. The Rejection Contained Material Errors In Fact, Law and Logic

Even a cursory review of the rejection based on Fisons '722 exposes several material deficiencies:

First, the Office Action contained incorrect factual assertions: the first sentence of the rejection incorrectly asserts that Fisons '722 teaches "the claimed compound" (when in fact it discloses a different compound)

and misleadingly asserts that the teaching of the claimed compound is in "an eye treatment' preparation" (when in fact the eye treatment of the reference is different from that claimed). In compounding the doubly incorrect first sentence, the Office Action further incorrectly asserts that the Fisons "treatment" appears to anticipate the present claims (when in fact Fisons teaches a different compound to treat a different disease).

Second, the Office Action failed to meet minimum legal criteria necessary to establish *prima facie* obviousness under 35 U.S.C. § 103. Rather than providing citation to at least one secondary prior art reference in an analogous art to establish the existence of the claimed compound in the prior art and to establish motivation to combine prior art teachings, the rejection relied on no specific citation to any prior art reference, but rather on unidentified "teachings" of the "detergent art!" How the teachings of the detergent art might be relevant to treatment of disease of the eye is one of the great mysteries in this case. If ever there were two non-analogous arts, surely detergents and disease treatment of the eye are clear examples. In the absence of evidence in analogous prior art in the record on appeal of the claimed compound and of a motivation to combine teachings, the rejection was incorrect as a matter of law.

Third, as a matter of logic, and assuming, *arguendo*, that some heretofore unknown basis exists for combining some generalized teachings of the detergent art with the disease treatment art, then the next great mystery of this case concerns how could "combining ingredients of the composition as taught by Fisons" in any plausible stretch of human imagination teach creation of a compound that is an entirely different chemical entity than was disclosed in Fisons?

Assuming, *arguendo* that Fisons has "broad teachings" of "optimal proportions," those teachings are limited to only the compounds disclosed in Fisons. Those teachings do not include teachings of any other compound, and certainly not any teaching of how to make a different chemical entity (which is what was claimed by applicants).

In summary, the rejection that was made to method claim 1 on the basis of Fisons '722 was materially erroneous in fact, law and logic.

d. Applicants Expressly Stated Their Belief That The Disease Treatment Subject Matter Was Patentable

During the original prosecution, broad method claim 1 eventually was replaced with broad method claim 18, and, after several rejections and minor amendments not relevant here, claim 18 was finally rejected under 35 U.S.C. § 103 as being unpatentable over Brown in view of Cox and G.B. '291 (directed to treatment of only Crohn's and obstructive airways diseases).

Applicants responded by filing an Amendment "B" After Final Under 37 C.F.R. § 1.116 that was received at the Patent Office Mail Room on February 16, 1995. In that response Applicants cancelled claim 18 "without prejudice."

In their remarks, applicants emphasized that:

> The amendment is necessary to eliminate a rejection under 35 U.S.C. § 103. *This amendment was not presented earlier because Applicants believed, and still believe, that the claim amendments and reasoning set forth in Amendment "A" filed*

> *July 11, 1994, were sufficient to overcome the rejection under 35 U.S.C. § 103.* This amendment should be entered because it places the application in better form for allowance or appeal, and the amendment does not require further searching or present any new issues.

Amendment "B" at 2-3. [Emphasis added.] A Notice of Allowability followed on March 16, 1995. These remarks alone make it absolutely clear that no express abandonment of the subject matter of cancelled claim 18 took place. To the contrary, applicants emphasized that at that time, despite canceling the claim in order to remove the rejection they "still believe" that the un-cancelled claims, including finally rejected claim 18, were patentable.

This above evidence in the prosecution history affirmatively shows that Fisons '722 was not even pertinent to the issue of patentability under 35 U.S.C. §§ 102, 103; that applicants denied unpatentability of claim 18; and that no abandonment of the eye disease subject matter took place.

e. The Reason Why Claim 18 Was Cancelled And Not Re-Submitted In A Co-Pending Application

The reason why claim 18 was cancelled and not re-submitted in a co-pending application is explained in the Declaration of Alison Blakey, the assignee's corporate patent attorney having responsibility for the application. She explained that the reason for cancellation of claim 18 was related to the then-perceived importance of patent protection for obstructive airways disease, viz., nedocromil sodium nebulizer. At that time Fisons was engaged in filing a New Drug Application with the FDA,

and Fisons was considering the benefit it would receive from a patent term of 17 years directed to treatment of obstructive airways disease. She also explained why no continuation application was filed. This error was due to a corporate acquisition that left Fisons with no in-house patent attorney at the critical time, and with no one else knowledgeable about the circumstances of the case. See, Reissue Declaration of Alison Blakey, ¶¶ 5-10. A copy of the Blakey Declaration is provided as Appendix 16.

For all of the above reasons the 3-step analysis of the recapture rule should be stopped at step 2, and the final rejection should be reversed on the ground that no subject matter was surrendered. There is not only an absence of evidence that any of applicants' amendments were "an admission that the scope of that claim was not in fact patentable," but also there is affirmative, reliable evidence that the applicants believed that the claim was, in fact, patentable. *Id.* (quoting *Seattle Box Co. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 826, 221 USPQ 568, 574 (Fed. Cir. 1984)).

E. Step 3: Whether The Reissue Claims Are Materially Narrowed In Other Respects To Avoid The Recapture Rule — Here the Reissue Claims Are Materially Narrowed

1. The Third Step Determination May Be Made By Comparison Of Scope Of The Reissue Claims To That Of The Cancelled Claims

Assuming, *arguendo*, that applicants made an admission of unpatentability of the broadly claimed subject matter of original

prosecution claim 18, the recapture rule should not be applied because the reissue claims are materially narrowed in comparison to the cancelled claim. *Pannu, supra,* 258 F.3d at 1371, 59 USPQ2d at 1600. According to the Federal Circuit the third step determination may be made by comparison of the reissue claims to the cancelled claim:

> Once we determine that an application has surrendered the subject matter of the cancelled or amended claim, we then determine whether the surrendered subject matter has crept into the reissue claims. Comparing the reissue claim with the cancelled claim is one way to do this.

Clement, supra, 131 F.3d at 1469, 45 USPQ2d at 1164. [Emphasis added.]

Such a comparison may lead to establishing a second exception to application of the recapture estoppel rule. *See, e.g., Pannu, supra; Hester, supra,* 142 F.3d at 1482-83, 46 USPQ2d at 1641. In *Hester, supra,* the Federal Circuit explained this exception as follows:

> . . . this principle, in appropriate cases, may operate to overcome the recapture rule when the reissue claims are materially narrower in other overlooked aspects of the invention. The purpose of this exception to the recapture rule is to allow the patentee to obtain through reissue a scope of protection to which he is rightfully entitled for such overlooked aspects.

Id. Thus, under *Hester, supra,* this exception to application of the recapture rule exists when there has been a material narrowing of the claim in an "overlooked" aspect. Here it is apparent that the eye disease

aspect of the inventive treatment was overlooked during the original prosecution.

The third step analysis was also exhaustively considered in *Clement, supra.* There the Federal Circuit provided several "principles" on how to ~~apply~~ make a determination in this step, particularly in fact patterns in which reissue claims that are broader than the cancelled claims in some aspects, but narrower in others, as is the fact pattern here. These principles are:

> (1) if the reissue claim is as broad as or broader than the cancelled claim in all aspects, the recapture rule does not apply . . .
>
> (2) if it's narrower in all aspects, the recapture rule does not apply . . .
>
> **(3) if the reissue claim is broader in some aspects, but narrower in others, then:**
>
> (a) if the reissue claim is as broad as or broader in an aspect germane to a prior art rejection, but narrower in another aspect unrelated to the rejection, the recapture rule bars the claim;
>
> **(b) if the reissue claim is narrower in an aspect germane to prior art rejection, and broader in an aspect unrelated to the rejection, the recapture rule does not bar the claim**, . . . *Ball* is an example of (3)(b).

Clement, supra, 131 F.3d at 1470, 45 USPQ2d at 1165. [Emphasis added.] In this regard, appellants will show that each and every one of claims 10-19 in this appeal is an example of principle (3) (b), and that therefore the recapture rule does not bar any of these claims.

2. The Scope of Each Reissue Claim Compared To That of Cancelled Claim 18

For the purpose of this step 3 determination, the cancelled claim is claim 18. As shown in detail in Appendix 14, the prior art rejection relevant to this issue is the rejection directed to the treatable diseases aspect of the claims. Although twenty-three prior art rejections were made, only one prior art rejection to a method of treatment claim made any reference to eye disease, and that rejection was so riddled with error as to be not credible.

Subsequently when an NDA for the reversible obstructive airways disease subject matter was about to be approved, claim 18 was cancelled in favor of a claim narrowly drawn to the reversible ~~eye~~ obstructive airways disease aspect of the broad claim. As such, reissue application claims 10-19 also qualify for the second, "material narrowing" exception to application of the recapture rule, because this eye disease subject matter was essentially overlooked during the original prosecution, particularly during the critical stage, and because the eye disease aspect of each and every reissue claim is narrower than the treatable disease aspect of cancelled claim 18.

All reissue claims are narrower in the aspect of diseases treatable than the cancelled claim 18, with broadest reissue claim 14 being directed to fourteen eye diseases, but cancelled claim 18 being directed to twenty-four eye, nasal, colon and airway diseases.

While the reissue claims are narrower in regard to the diseases treatable aspect, they are broader than cancelled claim 18 in regard to

the administration of the active ingredient aspect of the claims, as detailed above. Thus, all of the appealed claims 10-19 are examples of *Clement* principle "(3) (b)". Under this principle, the recapture rule does not bar any of these claims now on appeal. Because no other rejection was made to any of claims 10-19, it follows that not only should the rejection be reversed, but also that a notice of allowance should issue forthwith.

3. The Final Rejection Of Claims 10 And 15 Should Be Reversed Because Their Scope Is Materially Narrower In The Treatable Disease Aspect Of The Claims Than The Scope Of Cancelled Claim 18, And Their Scope Is Broader In The Unrelated Active Ingredient Administration Aspect

Reissue claims 10 and 15 are directed to only conjunctivitis eye disease and broadly require the administration of active ingredient aspect to be in an effective amount, in an ophthalmically acceptable formulation (claim 10) or aqueous pharmaceutical solution (claim 15). Thus, the scope of the treatable disease aspect of these claims is even narrower than that of reissue claim 14. These claims also are examples of principle 3(b) of *Clement*, *supra*, as more extreme examples of a difference in scope between the reissue claims and the cancelled claim, and rejection to reissue claims 10 and 15 should be withdrawn for the same reason.

4. The Final Rejection Of Claims 13 And 16; 12 And 17; 11 And 18 Should Be Reversed Because Their Scope Is Materially Narrower In The Treatable Disease Aspect Of The Claims Than Is The Scope Of Cancelled Claim 18, And Their Scope Is Broader In The Unrelated Administration Aspect

Reissue claims 13 and 16 are directed to only the seasonal allergic conjunctivitis disease, reissue claims 12 and 17 are directed to only the allergic conjunctivitis disease, and reissue claims 11 and 18 are directed to only the vernal conjunctivitis disease of the conjunctivitis sub-sub-group of eye diseases and each broadly requires the active ingredient to be in an effective amount, in an ophthalmically acceptable formulation (claims 11, 12, and 13) or aqueous pharmaceutical solution (claims 16, 17 and 18). The scope of the treatable disease aspect of these claims is even narrower than that of reissue claim 14 and/or claim 1. Thus, the rejection to these reissue claims should be withdrawn because these claims are also examples of principle 3(b) of Clement.

5. The Final Rejection Of Claim 19 Should Be Reversed

The final rejection of multiple dependent claim 19 should be reversed because each version of claim 19 depends from a claim whose final rejection should be reversed for the reasons set forth herein.

X. CONCLUSION

For all of the above reasons the final rejection of claims 10-19 be reversed in all respects.

Respectfully submitted,

COUDERT BROTHERS LLP

Date: March 24, 2003

By: 
Jon E. Hokanson
Reg. No. 30,069

COUDERT BROTHERS LLP
333 South Hope Street, Suite 2300
Los Angeles, California 90071
(213) 229-2900

APPENDIX 1

CLAIMS ON APPEAL

10. A method of controlling the symptoms of conjunctivitis comprising administering to the eye of a patient having conjunctivitis an effective amount of nedocromil sodium in an ophthalmically acceptable formulation.

11. The method of claim 10, wherein the conjunctivitis is vernal conjunctivitis.

12. The method of claim 10, wherein the conjunctivitis is allergic conjunctivitis.

13. The method of claim 10, wherein the conjunctivitis is seasonal allergic conjunctivitis.

14. A method of treatment of a disease selected from the group consisting of conjunctivitis, keratitis, allergic eyes, and anterior uveitis, which method comprises administering to the eye an effective amount of an ophthalmically acceptable aqueous pharmaceutical solution containing the active ingredient 9-thyl-6, -dihydro-4, 6-dioxo-10-propyl-4H-pyrano(3,2)quinoline-2, 8-dicarboxylic acid, or a pharmaceutically acceptable salt thereof.

15. The method of claim 14, wherein the disease is conjunctivitis.

16. The method of claim 15, wherein the disease is seasonal allergic conjunctivitis.

17. The method of claim 15, wherein the disease is allergic conjunctivitis.

18. The method of claim 15, wherein the disease is vernal conjunctivitis.

19. The method of claims 14, 15, 16, 17 or 18, wherein said active ingredient is nedocromil sodium.

APPENDIX 2

UNITED STATES PATENT NO. 5,443,833

US005443833A

United States Patent [19]

Clark et al.

[11] Patent Number: 5,443,833

[45] Date of Patent: Aug. 22, 1995

[54] **PHARMACEUTICAL COMPOSITIONS**

[75] Inventors: **Andrew R. Clark**, Loughborough; **Paul Wright**, Bramcote; **Julia H. Ratcliffe**, Gosport, all of England

[73] Assignee: **Fisons plc**, Ipswich, England

[21] Appl. No.: **82,804**

[22] Filed: **Jun. 25, 1993**

Related U.S. Application Data

[63] Continuation of Ser. No. 742,574, Aug. 7, 1991, abandoned, which is a continuation of Ser. No. 410,020, Sep. 20, 1989, abandoned, which is a continuation of Ser. No. 133,520, Dec. 16, 1987, abandoned.

[30] **Foreign Application Priority Data**

Dec. 23, 1986	[GB]	United Kingdom	8630767
Dec. 23, 1986	[GB]	United Kingdom	8630769
Dec. 24, 1986	[GB]	United Kingdom	8630904
Mar. 20, 1987	[GB]	United Kingdom	8706684

[51] **Int. Cl.**[6] **A61K 9/00**

[52] **U.S. Cl.** **424/400**; 424/489; 424/434

[58] **Field of Search** 424/489, 400, 450, 434; 546/97

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Primary Examiner—Thurman K. Page
Assistant Examiner—William E. Benston, Jr.
Attorney, Agent, or Firm—Marshall, O'Toole, Gerstein, Murray & Borun

[57] **ABSTRACT**

A method of treatment of a condition selected from the group comprising conjunctivitis, keratitis, 'allergic eyes', adenovirus infections, corneal homograft rejection, anterior uveitis, nasal polyps, vasomotor rhinitis, allergic manifestations of the nasopharynx, reversible obstructive airways disease, Crohn's disease, distal colitis and proctitis, which method comprises administration to a patient suffering from such a condition of a therapeutically effective amount of an aqueous solution containing, as active ingredient, 9-ethyl-6,9-dihydro-4,6-dioxo-10-propyl-4H-pyrano(3,2-g)quinoline-2,8-dicarboxylic acid or a pharmaceutically acceptable salt thereof. Also described are novel pharmaceutical compositions suitable for use in such methods of treatment.

3 Claims, No Drawings

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PHARMACEUTICAL COMPOSITIONS

This is a Continuation of U.S. application Ser. No. 07/742,574, filed Aug. 7, 1991, now abandoned; in turn a Continuation of Ser. No. 07/410,020 filed Sep. 20, 1989, now abandoned; in turn a Continuation of Ser. No. 07/133,520 filed Dec. 16, 1987, now abandoned.

FIELD OF THE INVENTION

This invention relates to methods of treatment and to novel pharmaceutical compositions for use in such methods.

DESCRIPTION OF THE PRIOR ARTS

In British Patent No 2022078 there are disclosed a number of pyranoquinoline compounds which are indicated for use in the treatment of reversible airway obstruction. Pharmaceutical compositions containing these compounds are also described, especially compositions in which the active ingredient is in powder form with a mass median diameter of from 0.1 to 10 microns. British Patent Application No 2157291A describes the particular utility of the disodium salt of one of these compounds, 9-ethyl-6,9-dihydro-4,6-dioxo-10-propyl-4H-pyrano(3,2-g)quinoline-2,8-dicarboxylic acid, in the treatment of reversible airway obstruction. Also described are powdered aerosol compositions of this salt for administration to the lung and physical forms of the salt which are especially suitable for formulation in this way.

BRIEF SUMMARY OF THE INVENTION

We have now surprisingly found that when it is administered in aqueous solution the same compound is efficacious in the treatment of a variety of disorders of the eye, notably conjunctivitis, as well as in the treatment of certain disorders associated with other organs.

Thus, according to the invention there is provided a method of treatment of a condition selected from the group comprising:

- conjunctivitis, keratitis, 'allergic eyes', adenovirus infections, corneal homograft rejection, anterior uveitis;
- nasal polyps, vasomotor rhinitis, allergic manifestations of the nasopharynx;
- reversible obstructive airways disease;
- Crohn's disease, distal colitis and proctitis, which method comprises administration to a patient suffering from such a condition of a therapeutically effective amount of an aqueous solution of 9-ethyl-6,9-dihydro-4,6-dioxo-10-propyl-4H-pyrano(3,2-g)quinoline-2,8-dicarboxylic acid or a pharmaceutically acceptable salt thereof.

By the term 'conjunctivitis' we mean inflammatory disorders of the conjunctiva commonly characterised by photophobia and irritation. The condition may be bacterial or vital and encompasses a number of specific types of conjunctivitis; for instance, seasonal allergic conjunctivitis, perennial allergic conjunctivitis, vernal catarrh (vernal kerato-conjunctivitis) , 'irritable eye' or 'non-specific conjunctivitis', Herpes Simplex Conjunctivitis, Herpes Zoster Conjunctivitis and phlyctenular conjunctivitis.

Similarly, by the term 'keratitis' we mean inflammation of the cornea which may involve its superficial surface ('superficial keratitis' including the localised form known as 'corneal ulceration') or be confined to the deeper layers ('interstitial keratitis'). Other particular forms of keratitis which may be mentioned include Herpes Simplex Keratitis and Herpes Zoster Keratitis.

Proctitis includes chronic (ie ulcerative) and non-specific proctitis.

DETAILED DESCRIPTION OF THE INVENTION

Pharmaceutically acceptable salts of the active ingredient include salts with metal cations, such as alkali metal cations. We particularly prefer the disodium salt which is commonly referred to as nedocromil sodium.

The solution is administered by a route appropriate to the condition being treated. For instance, administration may be to the eye, intra-nasally (e.g. as a nasal spray), by inhalation as a nebulised cloud or rectally as an enema.

We prefer administration of the solution to be by a route other than by inhalation. In particular, we prefer administration to be to the eye.

The solution may contain from about 0.1 to 10% w/v of the active ingredient. However, we prefer the active ingredient to be present at a level of less than 5% and more particularly less than 3% w/v, e.g. 0.5%, 1.0% or 2.0% w/v. The concentration of choice will depend of course inter alia on the nature of the condition to be treated, its severity and the mode of administration of the solution.

In addition to the active ingredient the solution generally contains one or more pharmaceutically acceptable additives. Examples of classes of additive which may be present are:

a) chelating or sequestering agents,
b) preservatives, and
c) viscosity-modifying agents.

Suitable chelating or sequestering agents include sodium carboxymethyl cellulose, citric, tartaric or phosphoric acid, and amino carboxylate compounds. The preferred chelating agent, however, is ethylenediamine tetraacetic acid or a salt thereof, especially its di-sodium salt.

The concentration of the chelating or sequestering agent should be such as to ensure that no precipitate of metal salts of the active ingredient occurs. A suitable concentration of chelating or sequestering agent may be from 0.005 to 0.5, e.g. 0.01 or 0.1% w/v.

The choice of preservative, where the solution contains a preservative, may depend on the route of administration. Preservatives suitable for solutions to be administered by one route may possess detrimental properties which preclude their administration by another route. For nasal and ophthalmic solutions, preferred preservatives include quaternary ammonium compounds, in particular the mixture of alkyl benzyl dimethyl ammonium compounds known generically as 'Benzalkonium Chloride'. For solutions to be administered by inhalation, however, the preferred preservative is chlorbutol. Other preservatives which may be used, especially for solutions to be administered rectally, include alkyl esters of p-hydroxybenzoic acid and mixtures thereof, such as the mixture of the methyl, ethyl, propyl and butyl esters which is sold under the tradename "Nipastat".

The concentration of preservative should be such as to ensure effective preservation of the solution ie such that bacterial growth in the solution is inhibited. For most preservatives the concentration will typically lie in the range 0.001 to 0.1% w/v. However, in the case of

chlorbutol acceptable concentrations are greater than 0.25% but less than 0.6% w/w ie the concentration of chlorbutol is 0.25 to 0.6%, preferably 0.3 to 0.55% e.g. 0.5% w/w.

Suitable viscosity enhancing agents which may be incorporated into the solution include carbomers ie polymers of acrylic acid cross-linked with a polyalkenyl polyether, aluminium magnesium silicate, methylcellulose, hydroxypropyl methylcellulose and other cellulose derivatives.

The viscosity of the solution will depend, inter alia, on the particular viscosity enhancing agent used and its molecular weight and on the target organ. However, the solution preferably has a viscosity of at least 100 cps, more preferably at least 200 cps and especially more than 400 cps, at a shear rate of 50 s^{-1}. The viscosity of the solution is preferably less than 10000 cps, more preferably less than 1000 cps and especially less than 500 cps, at a shear rate of 50 s^{-1}.

Viscosities are preferably determined using a rotational viscometer such as a Rheomat 30 (Rheomat is a Trade Mark), at a temperature of from 15° to 25° C. e.g. 20° C.

For applications which involve the solution being administered as a spray e.g. through a nasal pump, we prefer the viscosity enhancing agent to have a low viscosity at high shear rates, e.g. from about 100 cps to about 300 cps at 140 s^{-1}, and a high viscosity at low shear rates, e.g. from about 700 cps to about 1200 cps at 15 s^{-1}.

Viscosity enhancing agents which we prefer include hydroxypropyl methylcellulose and carbomers, in particular the carbomer sold as Carbopol 934, the viscosity of a neutralised 0.5% w/w aqueous dispersion of which lies in the range 29400 to 39400 cps and the heavy metal content of which is 0.002% or less. 10 The amount of viscosity-modifying agent required to achieve the desired viscosity will depend on the particular agent used and also on its molecular weight. However, we prefer to use up to about 2% w/w, e.g. 0.5 to 1.5% w/w of viscosity enhancing agent.

The solution may also contain other conventional excipients, e.g. sodium chloride, dextrose or mannitol, and buffers, e.g. sodium dihydrogen orthophosphate (sodium acid phosphate BP), di-sodium hydrogen phosphate (sodium phosphate BP) sodium citrate/citric acid, and boric acid/sodium borate. The proportion and concentration of excipients and buffers may be varied within fairly wide ranges, provided the resulting solution is stable and non-irritant when applied to the appropriate tissues. The maximum total concentration of excipients and buffers is preferably less than 5% w/v and more preferably less than 2% w/v. Solutions for rectal administration may contain bulking agents, e.g. methyl cellulose, to aid retention in the bowel.

The solution may be made isotonic with physiological fluids by the incorporation of a suitable tonicity agent e.g. sodium chloride. The solution typically contains from about 0.1 to 1.0, more typically 0.5 to 1.0% w/v sodium chloride.

Although physiological pH is about 7.4, we prefer the pH of the solution to be in the range 3.5 to 6, preferably 4 to 5.5. In this range of pH, the stability of the solution is enhanced, surprisingly with no deleterious effects such as undue tissue irritation.

The composition of the invention may be made up, for example, by dissolving the active ingredient, chelating or sequestering agent (if included) and excipients (if included) in freshly distilled water, adding to this solution an aqueous solution containing the preservative (if included), adjusting the pH if necessary, making the solution up to the desired volume with distilled water, stirring and then sterilising. Alternatively, the active ingredient, chelating or sequestering agent (if included) and excipients (if included) may be dissolved in a solution containing the preservative. Sterilisation is preferably performed by sterile filtration into a previously sterilised container. Where the preservative used is benzalkonium chloride, some complex formation may occur when the solutions of active ingredient and preservative are mixed. It may thus be necessary to use a higher concentration of preservative than is desired for the final product.

Aqueous solutions containing active ingredient, a viscosity enhancing agent, e.g. a carbomer, and, optionally, a preservative, e.g. benzalkonium chloride, may be prepared by dispersing the viscosity enhancing agent in an aqueous solution containing the preservative (if used) and the active ingredient, and then, if required, adjusting the pH, e.g. by addition of sodium hydroxide, and, if desired, further diluting the solution with water.

The solution of the preservative and the active ingredient may be made simply by dissolving the ingredients in water which is low in metal ions.

The solution is preferably made up at a temperature of from about 10° to 50° C., for example at room temperature.

The solution may be put up in unit dosage form, in which case preservatives may be incorporated, but are generally not necessary. Alternatively the solution may be put up in multi-dose form. In general it will be necessary to incorporate one or more preservatives into multi-dose solutions to ensure that the solution remains sterile after initial use.

Conventionally, unit doses of aqueous solutions for use in nebulisers are packed in glass or plastics ampoules which are broken open immediately prior to use. Such packaging is both wasteful and expensive to manufacture. Furthermore, the breaking-open of glass ampoules could lead to the formation of glass sherds which can be inhaled with the solution.

We have now found a form of packaging for single-dose solutions which overcomes the above-mentioned disadvantages. Thus, according to a further aspect of the invention, we provide a soft ampoule of plastics material sterile-filled with a unit dose of an aqueous solution containing, as active ingredient, 9-ethyl-6,9-dihydro-4,6-dioxo-10-propyl-4H-pyrano(3,2-g)quinoline-2,8-dicarboxylic acid or a pharmaceutically acceptable salt thereof, and sealed.

We prefer the plastics material to be permeable to carbon dioxide. Thus, when the ampoule is stored, carbon dioxide dissolves in the solution and the pH is lowered. Since the stability of the active ingredient is greater at lower pH, this has the effect of enhancing the stability of the solution.

Suitable plastics materials from which the ampoule may be manufactured include low-density polyethylene.

A plurality of ampoules may be connected to, and formed integrally with, an anchorage member which may be adapted to receive a label or writing, e.g. to identify the contents of the ampoules.

The plastics material may include a pigment or pigments such that the ampoules correspond in colour to the solution contained within them.

Multi-dose solutions may be packaged in volumes of 5 to 300 ml. Preferred volumes for inhalation compositions include 60, 120 and 240 ml. For nasal and ophthalmic compositions multi-dose packs preferably contain from 5 to 20 ml of solution.

We prefer multi-dose solutions to be packaged such that unit volumes of the solution to be administered can be accurately dispensed. The solution may, for example, be packaged in a flexible-walled container provided with a cap to receive the unit volume.

The dosage to be administered will of course vary with the condition to be treated, with its severity and with its location. However, in general for use in the eye a dosage of about 1 or 2 drops (e.g. from about 0.3 to 1.2 mg of active ingredient depending on the concentration of active ingredient) into the affected eye from 2 to 4 times a day is found to be satisfactory. More frequent dosage may, of course, be used if desired. For use in the nose a dosage of about 0.25 ml (e.g. from about 1.2 mg to 5.0 mg of active ingredient) is indicated.

For rectal administration a total daily dosage of from about 50 to 1000 mg of active ingredient, more preferably 100 to 400 mg, administered in smaller doses 2 to 4 times a day is found to be satisfactory. A dosage unit may conveniently contain from about 25 to 200 mg of active ingredient.

For administration by inhalation a daily dosage of from about 10 mg to 100 mg is, in general, found to be satisfactory. The daily dosage may be administered in divided doses, e.g. from 2 to 4 times a day. More frequent dosage may of course be used if required.

The aqueous solutions according to the present invention are advantageous in that they are longer acting, more acceptable to the patient, give rise to higher concentrations of active ingredient in target tissues, give rise to effective concentrations of active ingredient in target tissues for a longer time or are more stable than known similar formulations.

The invention is illustrated, but in no way limited, by the following Examples.

Example 1

Non-preserved nebuliser solution

Nedocromil Sodium	0.5% w/v
Sodium Chloride	0.79
Hydrochloric acid	q.s.
Purified Water	to 100

Nedocromil sodium (5 g) and sodium chloride (7.9 g) were dissolved in purified water (900 ml). The pH of the solution was adjusted to between 5 and 5.5 by addition of hydrochloric acid and the volume made up to 1000 ml with purified water.

The solution was sterile-filled into low-density polyethylene ampoules which were then sealed.

Example 2

Preserved nebuliser solution

Nedocromil Sodium	0.5% w/v
Sodium Chloride	0.79
Chlorbutol	0.5
Sodium hydroxide	q.s.
Purified Water	to 100

Chlorbutol (5 g) was dissolved in purified water (900 ml). Nedocromil sodium (5 g) and sodium chloride (7.9 g) were then added to the solution. The pH of the solution was adjusted to between 5 and 5.5 by addition of sodium hydroxide and the volume made up to 1000 ml with purified water.

The solution was filled into polyethylene bottles of 120 ml capacity.

Example 3

Nasal Solution

Nedocromil Sodium	1.00% w/v
Sodium Chloride	0.715
Disodium Edetate	0.01
Benzalkonium Chloride	0.02
Purified Water	to 100

Nedocromil sodium (100 g), sodium chloride (71.5 g) and disodium edetate (1 g) were dissolved in approximately 5 liters of purified water. To this solution a dispersion of benzalkonium chloride solution 50% USNF (4 g) in approximately 1 liter of purified water was added. The solution was made up to 10 liters with purified water, stirred for 30 minutes, filtered to remove any complex formed and then sterile filtered and filled into bottles.

Example 4

Opthalmic Solution

Nedocromil Sodium	2.00% w/v
Benzalkonium Chloride	0.01
Disodium Edetate	0.05
Sodium Chloride	0.55
Purified Water	to 100

Prepared by the method of Example 3 above.

Example 5

Viscous Nasal or Ophthalmic Solution

Nedocromil sodium	1.0% w/w
Disodium edetate	0.1
Benzalkonium chloride	0.01
Carbopol 934P	0.73
Sodium hydroxide	q.s.
Purified water	to 100

20 g of nedocromil sodium and 2 g of disodium edetate were dissolved in approximately 600 g of purified water. A dispersion of 0.808 g of Benzalkonium Chloride Solution 50% USNF in approximately 200 g of purified water was added and the resulting dispersion made up to 1000 g with purified water and stirred for 30 minutes.

The dispersion was filtered through a glass fibre prefilter and the first 100 ml discarded. The remainder of the filtered solution was filtered through a pre-sterilised 0.22 um membrane filter and the filtrate collected.

250 g of the filtrate was added to 4.15 g of Carbopol 934P and stirred until the Carbopol was fully dispersed. The pH of the dispersion was adjusted to between pH 5.5 and 5.8 by addition of 2M sodium hydroxide solution. The dispersion was mixed until a homogeneous uniform gel was formed. The gel was made up to 500 g with purified water, remixed and filtered through a 13 um stainless steel filter.

The viscosity of the solution at 20° C. and a shear rate of $50s^{-1}$ was found to lie in the range 420–480 cps.

Example 6

Enema Solution

Nedocromil Sodium	0.15% w/v
Nipastat	0.10
(Nipastat is a trademark)	
Sodium Chloride	0.812
Purified Water	to 100

Methyl cellulose or other agents may be added to aid retention of the solution in the bowel.

Example 7

Study of 2% Nedocromil Sodium Eye-Drops in the Treatment of Seasonal Allergic Conjunctivitis

32 patients (11 male, 21 female) with ages in the range 4 to 69 (average 25.2) participated in an investigation of the efficacy of an aqueous solution of nedocromil sodium in the treatment of seasonal allergic conjunctivitis. The solution used had the composition given in Example 4. One drop (0.04 ml) was administered per eye four times a day for four weeks.

At the end of the trial, both the patient and the supervising clinician were asked to rate the effectiveness of the treatment, using the following 0–3 scale:

0=no control of symptoms
1=slight control
2=moderate control
3=full control

In addition the patients were asked whether the eye-drops were an acceptable form of treatment.

For the 23 patients who completed the trial, the results were as follows:

Rating	No of patients: Patients' assessment	Clinicians' assessment
3	10	7
2	9	9
1	2	4
0	1	1

(One patient failed to record an opinion, and the clinician failed to record an opinion for two patients).

18 of the 23 patients recorded that they found the treatment acceptable.

We claim:

1. A method of treating a reversible obstructive airways disease comprising administering, by inhalation, to a patient suffering from, or susceptible to, such a condition the nebulized contents of an ampoule of carbon dioxide permeable plastics material filled with a unit dose of an aqueous pharmaceutical solution containing, as active ingredient, from 0.1 to 5% w/v of 9-ethyl-6,9-dihydro-4,6-dioxo-10-propyl-4H-pyrano(3,2-g)quinoline-2,8-dicarboxylic acid or a pharmaceutically acceptable salt thereof, the solution having a pH of 3.5 to 6.0.

2. The method of treatment according to claim 1, wherein the concentration of the active ingredient in the solution is from 0.1 to 1.0% w/v.

3. The method of treatment according to claim 1, wherein the active ingredient is nedocromil sodium.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,443,833

DATED : August 22, 1995

INVENTOR(S) : CLARK ET AL.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 3, line 8, "aluminium" should be --aluminum--.

Column 3, line 36, "less. 10 The" should be --less. ¶The--.

Signed and Sealed this

Second Day of April, 1996

Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks

APPENDIX 3

SUMMARY OF PROSECUTION OF THE FOUR APPLICATIONS AND THE TWO REISSUE APPLICATIONS

The original '520 application, entitled "Pharmaceutical Compositions" was filed on December 16, 1987. The '520 application relates to (i) methods of treatment of a variety of eye, nasal, colon and airway diseases using nedocromil acid or pharmaceutically acceptable salts thereof, such as nedocromil sodium as the active ingredient, which is administered in an aqueous solution and to (ii) novel pharmaceutical compositions for use in such methods. The aqueous solution is administered by a route appropriate to the condition being treated. Thus, for treatment of eye conditions, administration may be to the eye itself; for treatment of nasal conditions, intra-nasally with a nasal spray; for reversible obstructive airway disease, by inhalation as a nebulised cloud; and, for treatment of colon conditions, rectally as an enema.

Each of the '520, '020 and '574 applications was prosecuted to final rejection, and was followed by the filing of a continuation application. The last continuation application in the series, the '804 application, filed June 25, 1993, included claims 23-25 that were directed only to the treatment of reversible obstructive airways disease, and with a very narrow scope for the administration of the aqueous solution of the active ingredient aspect of the claims. Application claims 23-25 issued as claims 1-3 of the '833 patent on August 22, 1995.

In the '578 reissue application, in an Office Action dated November 22, 1999, claims 4-13 were rejected under 35 U.S.C. § 112, ¶ 2 for the reasons that in regard to claim 4 quotation marks were not permissible and the word "an" should have been omitted. In an amendment mailed December 8, 1999, claim 4 was amended to delete the quotation marks and to replace "an" with -the--.

In an Office Action dated April 4, 2000, prosecution on the merits in the reissue application was closed, but claim 4 was required to be submitted as a "new claim 4, incorporating all said changes" rather than be amended by simply providing instructions to amend the claim. In an amendment mailed June 6, 2000, a "new" amended claim 4, including all of the changes, was submitted.

In an Office Action dated April 18, 2001, with a new assistant examiner, claims 1-13 were " . . . rejected under 35 U.S.C. § 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based." The examiner also suggested that claim 4 be submitted as a new claim 14. In an amendment mailed July 9, 2001, claims 4-9 were cancelled and new claims 14-19 were submitted. New claims 14-19 replaced and were substantively identical to prior reissue application claims 4-9, as previously amended. Argument was then also presented that the recapture rule did not bar claims 1-3 and 10-19, which argument was not accepted, in a subsequent final rejection on March 18, 2002.

On June 10, 2002 a continued prosecution application ("CPA") was filed, without amendment. On June 28, 2002, another final rejection was made, on the same basis as made earlier, i.e., an improper recapture of broadened subject matter surrendered during application for the patent upon which the present application is based. The body of the final rejection is reproduced below:

> Claims 1-4 and 10-19 are rejected under 35 U.S.C. § 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. . . . [Citations omitted]. . . A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that applicant previously surrendered during prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. § 251 and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.
>
> Applicants are seeking a reissue of U.S. Patent Number 5,443,833 issued on August 22, 1995. U.S. Patent Number 5,443,833 contains Claims 1-3, which are drawn to a method of treating a reversible obstructive airway disease. The instant reissue application contains the same three claims as well as Claims 4-13. Claims 4-13 were present in the prosecution of the original application but were cancelled after a final rejection filed February 13, 1995. The scope of the Claims 4-13 is broader than Claims 1-3 being that Claims 4-13 are drawn to methods of treating conjunctivitis, keratitis, allergic eyes and anterior uveitis. These claims are drawn to subject matter that was surrendered during the original prosecution of the application.

> Applicants' understanding of these facts is evidenced in their Reissue Declarations filed with the instant application, more specifically in Paragraphs 7 and 8 of the Declarations. Therefore, Claims 1-13 cannot be allowed in the instant reissue application because the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application. . . . .
>
> It is the position of the Examiner position that the claims admittedly have distinguishing features but these features fail to patentably define or distinguish the claims over the scope of the claims that were cancelled in order to obtain the patent in the parent application.

Final Rejection dated June 28, 2002, at 2-3.

APPENDIX 4

CONDITIONS TREATABLE BY THE INVENTIVE SOLUTION

The 1 Markush Group:	Variety of eye, nasal, colon and airway diseases
The 3 Sub-Groups:	Eye, Nasal, Colon
The 6 Eye Sub- Sub-Groups:	(1) **Conjunctivitis**;[10] (2) **Keratitis**; (3) **Allergic Eyes**; (4) Adenovirus Infections; (5) Corneal Homograph Rejection; and (6) **Anterior Uveitis**
The 3 Nasal Sub –Sub-Groups:	(1) Nasal Polyps; (2) Vasomotor Rhinitis; (3) Allergic Manifestations of the Nasopharynx
The 3 Colon Sub- Sub-Groups:	(1) Crohn's Disease; (2) Distal Colitis; and (3) Proctitis

[10] The four sub-sub-groups of eye diseases bolded are the only four of the six that are claimed in the present reissue application.

The 24 Diseases:

(1) Allergic eyes; (2) adenovirus infections; (3) corneal homograft rejection; (4) anterior uveitis; (5) **seasonal allergic[11] conjunctivitis**; (6) **perennial allergic conjunctivitis**; (7) **vernal catarrh (vernal kerato-conjunctivitis)**; (8) irritable eye or non-specific conjunctivitis; (9) Herpes Simplex Conjunctivitis; (10) Herpes Zoster Conjunctivitis; (11) phlyctenular conjunctivitis; (12) superficial keratitis; (13) Herpes Simplex Keratitis; (16) Herpes Zoster Keratitis; (17) nasal polyps; (18) vasomotor rhinitis; (19) allergic manifestations of the nasopharynx; (20) reversible obstructive airways disease; (21) Crohn's disease; (22) distal colitis; (23) ulcerative proctitis; and (24) non-specific proctitis

'833 patent, 1:42-2:5.

[11] The three specific conjunctivitis diseases bolded and underscored are the only three diseases that are specifically claimed in the reissue application.

APPENDIX 5

Application of Wadlinger

Application of Robert L. WADLINGER et al.

Patent Appeal No. 8997.

United States Court of Customs and Patent Appeals.

May 23, 1974.

Proceeding in the matter of the application for the reissue of patent No. 3,308,069 for catalytic composition of a crystalline zeolite. An appeal was taken from the decision of the Patent Office Board of Appeals which affirmed the rejection of claims 16, 17, and 19 of application Serial No. 806,753. The United States Court of Customs and Patent Appeals, Rich, J., held that claims 16, 17, and 19, directed to the use of zeolite beta as a catalyst for four hydrocarbon conversion reactions recited therein were unobvious from two Plank references which nowhere disclosed zeolite beta; that method of use claims 16, 17 and 19 defined an unobvious contribution to art of converting hydrocarbons; that although both cancelled claims and claims on reissue application may have been directed to same process, scope of cancelled claims was broader than scope of reissue claims; that the statute respecting the reissue of patent for invention disclosed in the original patent when any patent is through "error" deemed invalid by defective specification or drawing or because the patentee claimed more or less than he had a right to claim, instead of using the words "inadvertence, accident or mistake" appearing in corresponding prior statute, did not involve a substantive change; that in applying standards of obviousness to method of use claims applicant was not required to show unexpected superior results.

Reversed.

Miller, J., filed a specially concurring opinion.

1. Patents ⇐18

Claims 16, 17, and 19, directed to the use of zeolite beta as a catalyst for four hydrocarbon conversion reactions recited therein were unobvious from two Plank references which nowhere disclosed zeolite beta. 35 U.S.C.A. § 103.

2. Patents ⇐18

Method of use claims 16, 17 and 19 defined an unobvious contribution to art of converting hydrocarbons. 35 U.S.C. A. § 103.

3. Patents ⇐141(2)

Although both cancelled claims and claims on reissue application may have been directed to same process, scope of cancelled claims was broader than scope of reissue claims which, in more fairly fingerprinting processes, resulted in claims which differed from cancelled claims in scope of legal protection afforded, and thus claims on reissue application were allowable under statute pertaining to reissue of defective patents. 35 U.S.C.A. § 251.

4. Patents ⇐141(2)

The statute respecting the reissue of patent for invention disclosed in the original patent when any patent is through "error" deemed invalid by defective specification or drawing or because the patentee claimed more or less than he had a right to claim, instead of using the words "inadvertence, accident or mistake" appearing in corresponding prior statute, did not involve a substantive change. 35 U.S.C.A. § 251.

5. Patents ⇐18

In applying standards of obviousness to method of use claims applicant was not required to show unexpected superior results. 35 U.S.C.A. § 103.

6. Patents ⇐141(2)

Applicant for claims on reissue was not required to show unexpected properties to establish "error" within statute pertaining to reissue of defective patents. 35 U.S.C.A. § 251.

7. Patents ⇐134

Patentability of reissue claims is determined by application of law which exists during prosecution of reissue application rather than law at date of issuance of original patent, where there has been a change since then. 35 U.S.C.A. § 251.

8. Patents ⇐134

Reissue patent application could benefit from change in law brought about by decisional law.

Richard K. Stevens, Arlington, Va., attorney of record, for appellants. O. G. Hayes and R. W. Barclay, New York City, of counsel.

S. Wm. Cochran, Washington, D. C., for the Commissioner of Patents. Robert D. Edmonds, Washington, D. C., of counsel.

Before MARKEY, Chief Judge, and RICH, BALDWIN, LANE and MILLER, Associate Judges.

RICH, Judge.

This appeal is from the decision of the Patent Office Board of Appeals affirming the rejection of claims 16, 17, and 19 of application serial No. 806,753, filed March 4, 1969, for reissue of patent No. 3,308,069, granted March 7, 1967, for "Catalytic Composition of a Crystalline Zeolite." We reverse.

The Invention

The invention relates to synthetic zeolites, methods of making them, and hydrocarbon cracking conversion processes using them as catalysts. Appellants' application includes claims drawn to zeolite compositions represented by the following patent claim allowed in this reissue application:

2. A crystalline synthetic catalyst material having the composition:

$$\left[\frac{X}{n}M(1 \pm 0.1 - X)H\right] AlO_2 YSiO_2 WH_2O$$

where X is less than 1, Y is greater than 5 but less than 100, W is up to about 4, M is a metal, and n is the valence of M, said material being characterized by an X-ray powder diffraction pattern essentially the same as that shown in Table 4.

The application refers to this composition as "zeolite beta" and so will we.

Appellants' original application for the patent they seek to reissue contained claims drawn to zeolite beta, methods of preparing the zeolite, and, as will later be explained in more detail, catalytic conversion of hydrocarbons utilizing the zeolite compositions. The claims to the zeolite and the methods of making it were allowed in the original application and are reallowed here, appearing as claims 1 through 14 in the reissue application. The issue here involves process claims to the use of zeolite beta as a catalyst for the cracking of hydrocarbons. Claim 19 reads:

19. In a process for conducting in the presence of a solid porous catalyst an isomerization, disproportionation, polymerization, or alkylation hydrocarbon conversion reaction characterized by a heat of reaction not less than zero, the improvement which comprises contacting charge hydrocarbons for said reaction at conversion conditions with a crystalline aluminosilicate catalyst at least partially in the hydrogen form resulting from treatment of the zeolite defined in claim 2 with a fluid medium containing ions selected from the class consisting of hydrogen ions and ammonium ions.

Claims 16 and 17 read:

16. The process of claim 19 wherein said fluid treating medium also contains metal cations.

17. The process of claim 19 wherein at least a portion of the ammonium ions in said treating medium are complex ammonium ions.

The Relevant Prosecution History of the Original Application

The original application was aptly characterized by the board as containing, in addition to the composition and

method-of-making claims, claims which are generic to all catalytic conversions with the novel zeolite, as well as claims directed to three specific types of conversion reactions: polymerization, alkylation, and isomerization. The method-of-use claims were rejected by the examiner in the original application "as the obvious use of the claimed crystalline zeolite," since "Plank et al. (II)[1] discloses the claimed use of a similar crystalline zeolite as a catalyst for the conversion of hydrocarbons. In their second response appellants stated:

> Applicants do not agree with the Examiners that the claims to the use of this novel catalyst are obvious in view of the prior art; however, in order to expedite issuance of this application but without setting a precedent on this point for future cases, applicants have cancelled claims 15–25 [the method-of-use claims] without prejudice in favor of the allowed claims.

The Basis for Reissue

Appellants base their claim for reissue under 35 U.S.C. § 251, as stated in the oath of the reissue application, upon the fact that

> * * * during the prosecution of the application, applicants did not understand all of the inherent characteristics of the claimed compositions, more particularly that certain of these compositions exhibited unique properties when used as catalysts in a selected class of catalytic hydrocarbon conversion reactions as recited in [the] claims * * * and it was not until after the patent issued that it was realized that claims of the scope of [these] claims * * * should have been included in this application based on the disclosure therein.

Thus, appellants' argument is that, under the law which governed the prosecution of their original application, appellants understood that the patentability of their method-of-use claims was determined by whether appellants could show the existence of unexpected or superior results in the use of the composition; and appellants, being unable to show such superior results, cancelled the claims directed to the use of the zeolite in the original application. Appellants filed the reissue application, however, because of their knowledge of what appeared to them to be unique superior properties of zeolite beta as a catalyst for cracking hydrocarbons, properties which they refer to as "inherent characteristics" of zeolite beta.[2]

The Rejections

As noted by the board, the claims on appeal stand rejected on two grounds:

> (1) The claims are improper reissue claims under 35 U.S.C. § 251 because appellants' deliberate cancellation of claims similar in scope in the original case does not involve error within the meaning of the statute; and

1. U. S. Patent No. 3,140,253, issued July 7, 1964.

2. Much was made at oral argument of the fact that appellants may not have discovered the superior results of the use of zeolite beta *until after issuance* of the original patent. See Reeves Brothers, Inc. v. U. S. Laminating Corp., 282 F.Supp. 118 (D.C. 1968), and Ex parte Ziherl, 116 USPQ 162 (Pat.Off.Bd.Appls.1957). The record before this court dealing with the question is scanty. The reissue oath, as already noted, said only that appellants "did not understand all of the inherent characteristics of the claimed compositions" during the prosecution of the original application. At oral argument appellants' attorney again spoke of the properties of the zeolite as "inherent" but noted that appellants "learned of the great value (of the zeolite catalyst) after the patent actually issued." This latter discovery was, in the view of appellants' attorney "a favorable thing because we [appellants] could not have inserted this specific claim before the patent issued."

We have studied the opinion of the board and have concluded that alleged *later discovery* of the superior performance of zeolite beta was not treated by the board as a reason for finding lack of "error" within the meaning of § 251. Accordingly, we do not deal with it here.

(2) The claimed process is unpatentable under 35 U.S.C. § 103 as being the obvious use of the claimed zeolite, with the Plank et al. patents being referred to in support of this rejection.

OPINION

The Obviousness Issue

Taking the second issue first, the board agreed with the examiner that the method-of-use claims were "directed to an obvious use of the claimed aluminosilicate" in view of two patents to Plank et al.[3] The position of the examiner was, first, that in view of the Plank patents "one of ordinary skill in this art would conclude that the crystalline aluminosilicate zeolites * * * would also be useful as catalysts for hydrocarbon conversion reactions," and, secondly, the affidavit submitted did not establish the existence of unexpected results in the use of the zeolite in all of the four reactions claimed. The board agreed with both rationales. Dealing with the test for determining the obviousness of the method-of-use claims, the board further expressed agreement with the examiner that the case was controlled by a Board of Appeals decision, Ex parte Kuehl, which, although unpublished, involved an application assigned to the same corporation as the application on appeal here. That decision of the board was reversed by this court last term. In re Kuehl, 475 F.2d 658 (Cust. & Pat.App.1973).

In *Kuehl*, where the facts were very similar to those here, we unanimously agreed that 35 U.S.C. § 103 requires that the obviousness of a method-of-use invention is not to be determined by asking, as the board did here, whether "one of ordinary skill in this art would conclude that the crystalline aluminosilicate zeolites described and claimed herein would also be useful as catalysts for hydrocarbon conversion reactions." Utilizing the very language of our opinion in *Kuehl*, we find the proper application of the statutory test of § 103, as enunciated by the Supreme Court in Graham v. John Deere Co., 383 U.S. 1, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966), and the reasons why the examiner and the board erred here, to be as follows (emphasis added):

> The issue here concerns primarily the meaning of the terms "prior art" and "subject matter as a whole" in § 103, and specifically *whether appellant's zeolite composition is in any way to be considered as "prior art" for the purposes of applying the statute.* Appellant says that the board's decision holding the claims to the method of using the zeolite obvious in view of * * * [the Plank patents] "necessarily utilizes as 'prior art' appellant's own disclosure" of the zeolite. To the extent that the board may have affirmed the examiner's view that the process claims represented "obvious use of the * * * catalyst for the conversion of hydrocarbons," this appears to be the case. The examiner's language does appear to treat incorrectly the * * * zeolite as part of the prior art. The correct application of the test of § 103 requires that the claims on appeal not be judged against any prior art other than * * * [the Plank patents].

[1, 2] We hold that the claims directed to the use of zeolite beta as a catalyst for the four hydrocarbon conversion reactions recited therein are unobvious from the two Plank references. While the Plank references describe, as noted by the board, "a considerable variety of known aluminosilicate zeolites and disclose their utility for hydrocarbon conversion reactions," including those *reactions* recited in the appealed claims, the references nowhere disclose zeolite beta. And, as we said in *Kuehl*, "the process 'invention as a whole' includes the use of the * * * zeolite and one having no knowledge thereof would not find it obvious to crack hydrocarbons using it as a catalyst." Judging the obviousness under § 103 of the method-of-use claims in similar fashion here, we conclude that they define an unobvious contribution to

3. Nos. 3,140,251 and 3,140,253, issued July 7, 1964.

the art of converting hydrocarbons. See In re Schneider, 481 F.2d 1350, 1356 (Cust. & Pat.App.1973). Accordingly, the rejection under § 103 is reversed.

The Reissue Question

The second basis for the denial of claims to the methods of use of zeolite beta is that they are improper claims for reissue under 35 U.S.C. § 251 because appellants deliberately cancelled claims of similar scope in the prosecution of their original patent, wherefore there is no "error without any deceptive intention," within the meaning of § 251.[4]

The original application contained claims which were directed broadly to "catalytic conversion of hydrocarbons" and also claims which were directed to three specific types of such reactions, including in particular "alkylation," "isomerization," and "polymerization." As previously noted, all such method claims were cancelled from the original application.

The main thrust of the examiner's rejection and the board opinion is to be found in the following quotation from the Examiner's Answer:

> Claims 16, 17 and 19 stand rejected as improper claims in this reissue. Claims of similar scope were deliberately cancelled by appellants' in the parent case thereby estopping appellants' [sic] from asserting error or inadvertence in applying for a reissue as required by 35 U.S.C. § 251. It is an established principle of law that the "deliberate withdrawal of rejected claim(s) in order to obtain (a) patent does not involve inadvertence or error justifying reissue of (a) patent; thus, claim(s) of reissue application (are) rejected where (they are) *similar in scope* to cancelled original claim(s), ["] (emphasis added). Nicherson [sic] v. Bearfoot Sole Co., Inc., (CA 6) [311 F.2d 858] 136 U.S. P.Q. 96[5] *accord,* McCullough Tool Co. v. Well Surveys Inc. (CA 10) [343 F. 2d 381] 145 U.S.P.Q. 6; In re Handel [312 F.2d 943, 50 CCPA 918] (CCPA) 136 U.S.P.Q. 460; Haliczer v. United States [356 F.2d 541, 174 Ct.Cl. 507] (U.S.Ct.Cls.) 148 U.S.P.Q. 565.

Appellants do not quarrel with the legal basis for the rejection of reissue claims under § 251 where claims "similar in scope" have been cancelled in the prosecution of the original application, but contend that the claims which were cancelled in their original application were not similar in scope to the claims on appeal, relying for authority upon three decisions by this court, In re Willingham, 282 F.2d 353, 48 CCPA 727 (1960); In re Wesseler, 367 F.2d 838, 54 CCPA 735 (1966); and In re Petrow, 402 F.2d 485, 56 CCPA 710 (1968), which broadly support the proposition that claims of a scope narrower than claims cancelled from the original application may be obtained by reissue.

The board apparently agreed with the above proposition of law, but distinguished the cases on the ground that here "the rejected claims are of substantially the same scope as those cancelled from the original application." Most of the board's opinion on this point is dis-

4. § 251. *Reissue of defective patents* [First para. only]

> Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Commissioner shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue.

5. The examiner was fleshing out USPQ headnote 3 in the *Nickerson* case by his parenthetical additions. The headnoted text was a quotation from the examiner raising a question left undecided by the court, which held the claims sued on "invalid for want of invention."

cussion of the fact that, with respect to the four specific hydrocarbon conversion *reactions* claimed in the reissue application, "no single original claim is directed to the exact grouping which is now claimed" in what the board referred to as a "Markush-type grouping."

As noted earlier, the original application contained claims broadly drawn to the "catalytic conversion of hydrocarbons," which claims the board considered to be "generic to *all* catalytic conversons with the novel zeolite," including the four conversions claimed in the reissue application, and also contained claims specific to three of the four conversion reactions claimed in the appealed claims, namely, isomerization, polymerization, and alkylation, to which the appealed claims add disproportionation. The board did not feel that these differences in the *form* of claiming—i.e., specific claims vs. a Markush grouping—mitigated against the claims being held to be of "substantially the same scope" for application of the rule against "recapture" by reissue of previously cancelled claims.

Appellants' second reason why there is a lack of similarity in scope between the cancelled claims and the appealed claims relates to the *form of the zeolite* which is used in the method of the appealed claims. Appellants' brief explains their argument:

> All of the claims, both those rejected and those cancelled, relate to the type of zeolite of claim 2, however, the specification indicates that the zeolites of claim 2 may be used as is or
>
> "catalytic materials can be prepared by calcining the original sodium form zeolite beta and/or by replacing the major portion of the sodium in the zeolite with other metallic and/or ammoniacal ions. If the calcination is carried out prior to ion exchange, some or all of the resulting hydrogen ions can be replaced by metal ions in the ion exchange process." (See specification, col. 5, lines 17–23).
>
> * * * * * *

The rejected claim 19 on the other hand [unlike the cancelled claims] relates to using the zeolite of claim 2 which has been treated with a fluid medium containing hydrogen or ammonium ions. Rejected claim 16 relates to using a zeolite of claim 2 which has been treated with a fluid medium containing hydrogen or ammonium ions and further containing metal ions. The rejected claim 17 relates to using a zeolite of claim 2 which has been treated with a fluid medium containing ammonium ions, at least a portion of which are complex ammonium ions.

Thus, it is clear that *the rejected claims are referring to a different catalyst than were* [*sic*] *claimed in cancelled claims of the original application.*

The board's view on appellants' argument relating to a difference in the claimed form of the zeolite was that the appealed claims were still of substantially the same scope as the cancelled claims. The board said:

> Original claim 15 shows the zeolite containing hydrogen and metal ions, and original claim 16 shows the zeolite containing complex ammonium and metal ions. The further limitation that the aluminosilicate catalyst at least partially in the hydrogen form results "from treatment of the zeolite defined in claim 2 with a fluid medium containing ions selected from the class consisting of hydrogen and ammonium ions" does not substantially change the scope of the claim because this is but the conventional manner of treating the zeolites.

Appellants respond to the board's argument by noting, correctly we think, that the specification shows that the catalysts of claim 2 already are at least partially in the hydrogen form, and further, that treatment may be by *either* calcining or ion exchange, whereas the appealed claims specifically recite only the catalyst resulting from treatment of the zeolite with a fluid medium containing hydrogen or ammonium ions. It is

apparent, therefore, that there is indeed a difference in claim scope, at least with respect to the form of the zeolite catalyst, between the invention now claimed and the invention covered by the cancelled claims. It remains to determine whether such a difference is sufficient to satisfy the requirements of § 251 as construed by the courts.

A basic statement of the law was made by us in In re Willingham, supra, 282 F.2d at 357, 48 CCPA at 733 where we said:

> The deliberate cancellation of a claim of an original application in order to secure a patent cannot ordinarily be said to be an "error" and will in most cases prevent the applicant from obtaining the cancelled claim by reissue. The extent to which it may also prevent him from obtaining other claims differing in form or substance from that cancelled necessarily depends upon the facts in each case and particularly on the reasons for the cancellation.

The question here, then, is whether the difference is one "in form or substance" which, as a matter of law, will justify the allowance of the appealed claims. We believe that it is, under prior decisions of this court.

[3] In re Petrow, supra, dealt with a very similar argument. The appellants there maintained that "the controlling feature in the present case is the fact that applicants are not attempting to recapture the same or an immaterially different claim from that cancelled * * *." In that case the applicants, during prosecution of their original application, abandoned claim 4 directed to a compound of betaine and chloral and sought through reissue to claim the identical compound in claim 10, which, however, in addition to the limitations of the cancelled claim, described the compound in more detail by reciting more of its inherent properties. Responding to the argument that under *Willingham* there could be no "error" justifying reissue of the patent under these circumstances, we said, 402 F.2d at 488, 56 CCPA at 713:

> We feel that the fact that claim 10 recites more inherent properties of the disclosed compound than does claim 4, so as to more fairly "fingerprint" it, results, under the circumstances shown, in a claim differing in form, as contemplated by the language quoted from In re Willingham, supra, as well as presenting a claim having a different scope of legal protection. While claim 10 may be directed to the same subject matter, that is, the disclosed invention, it does not necessarily follow that the scope of legal protection afforded it is the same as that of claim 4.

We think similar considerations govern the result here. While both the cancelled claims and the appealed claims may be *directed* to the same process, the scope of the cancelled claims was indeed broader than the scope of the appealed claims which, in more fairly fingerprinting the processes, results in claims which differ from the cancelled claims in the scope of legal protection afforded. Accordingly, we do not agree with the board that there can be no "error" within the meaning of § 251.

It is noted that part of appellants' argument has centered on In re Wesseler, 367 F.2d 838, 54 CCPA 735 (1966), where this court cast considerable doubt on the correctness of its prior statement in In re Byers, 230 F.2d 451, 454, 43 CCPA 803, 805 (1956), which reads:

> The use of the word "error" in that sentence [of 35 USC 251] instead of the words "inadvertence, accident or mistake," which appeared in the corresponding section (35 U.S.C. § 64, Section 4916 R.S.) of the patent statutes prior to the recodification of 1952, does not involve a substantive change, and the same type of error is necessary to justify a reissue after the enactment of the Patent Act of 1952 as before * * *.

Appellant says of *Wesseler*,

> According to this case, the error must occur only *without deceptive intention* and not through inadvertence accident or mistake as required by the old statute and In re Byers which is relied upon by the Examiner. Based upon this case, reliance upon In re Byers is of doubtful validity. The In re Wesseler case was decided some 10 years later than In re Byers and notes that there is no authority cited in the In re Byers case for the proposition that the old and new patent statutes contemplated the same type of error in 35 U.S.C. 251.

In addition, in *Wesseler* we did state that the court in *Byers* "ignored the *fact* that the new reissue statute broadened the term 'error' by not limiting it to 'error' that had arisen through 'inadvertence, accident or mistake'."[6]

[4] Appellants' argument has led us to review the legislative history of § 251 and the basis for our statement in *Wesseler*. We now conclude that in *Byers* this court was correct in noting that the substitution of "error" in § 251 for "inadvertence, accident, of mistake" did not involve a substantive change. See Federico, "Commentary on the New Patent Act," 35 U.S.C.A. p. 43. We would be hard-pressed to think of examples of situations which would be "error" and not be encompassed by one or the other of "inadvertence, accident, or mistake." "Inadvertence" and "accident" may imply something other than deliberate action, but "mistake" has a broad sweep and is certainly inclusive of actions taken in full consciousness. In Tee-Pak v. St. Regis, cited in note 6, supra, the Court of Appeals said, "a deliberate and intentional amendment to a claim may be error without deceptive intention." The primary definition of "mistake" is "to choose wrongly" (Webster's Seventh New Collegiate Dictionary).[7] This court, in its decisions both before and after *Wesseler*, has made it clear that a reissue applicant is, at most, prevented by interpretations of the language of § 251, and its predecessor statute R.S. 4916, from obtaining claims which are of the same scope as the claims previously cancelled in the original application. As for obtaining claims on reissue which are different, no prohibition arises merely because of the language of the reissue statute. Still apropos and basic is our statement in *Wesseler*:

> We think the term "error," arising as it does in a remedial provision designed to advance both the rights of the public and the inventor, is to be interpreted as Congress has stated it, "error without any deceptive intention," and in light of Supreme Court decisions favoring the liberal construction of reissue statutes in order

6. Recently, the accuracy of these statements in *Wesseler* was challenged by the District Court opinion in St. Regis Paper Co. v. Tee-Pak, Inc., 352 F.Supp. 309 (N.D.Ohio 1973), rev'd 491 F.2d 1193 (6th Cir. 1974). See discussion in Pat. Law Perspectives, Dev. A.8[1]–19, Rel. No. 4/1973.

7. It is unnecessary in this case to go into the meanings of the old and new reissue statutes exhaustively. However, we deem it instructive to note the following definition from Webster's New International Dictionary (2d Ed. 1937):

> *mistake* n. * * * 2. *Law.* Misconception or error of the mind leading a person to do an act which he otherwise would not have done; also the act or omission so arising, as an intentional act or omission arising from ignorance, surprise, imposition, or misplaced confidence.

Adopting such a definition of "mistake," it seems altogether superfluous to argue that "error without deceptive intention" is substantively broader than "error [which] has arisen by inadvertence, accident, or mistake, and without any fraudulent or deceptive intention," which is the old statutory language. In the absence of any revealing legislative history, probably the best that can be said is that the 1952 Act is a recodification of the old statute in more concise, modern statutory form, *omitting unnecessary words*. That would conform to the writer's personal recollection, as one of the drafters of the section, of what they intended to do. What we now feel is that this language of the former statute is quite as broad as the language of § 251 which replaced it, notwithstanding some cases which construed it narrowly.

to secure to inventors protection for what they have actually invented.

See In re Richman, 409 F.2d 269, 56 CCPA 1083 (1969), holding there was "error without any deceptive intention" under § 251 where the reissue claims differed in scope from cancelled claims and also found, as in *Wesseler*, that "while appellant *acted* 'deliberately', he did so in error."

Appellants' Unexpected Results

Part of the basis for the board's affirmance of the examiner's rejections under both sections 103 and 251 is an alleged insufficiency of appellants' showing of unexpected results of the use of their zeolite in the four hydrocarbon reactions claimed. The board found that "Even assuming that appellants have established unexpected results for isomerization it is clear that there is no sufficient showing as to disproportionation, polymerization, and alkylation." Since each member of the Markush-type grouping of reactions of the appealed claims "must be allowable individually or the whole group fails," the board, applying the law as it was before our decision in *Kuehl*, found the invention obvious under § 103 and, in addition, found no "error" under § 251.

[5] As respects § 103, there is no question but that the change in the law brought about by *Kuehl*, particularly in its overruling of In re Saunders, 154 F. 2d 693, 33 CCPA 1001 (1946), means that in applying the standards of § 103 to the appealed claims we need not consider whether appellants have established unexpected superior results in the use of zeolite beta because under *Kuehl* they need not show such results.

With respect to the question whether there was "error" within § 251, it is not so clear whether the unexpectedness of appellants' results must be examined. Part of the rationale of the board for the rejection under § 251, in addition to the estoppel rationale dealt with earlier, was that appellants committed no "error" by not originally pursuing the method-of-use claims since, in fact, they had no unexpected results and thus were never entitled to method-of-claims in the first place.

[6, 7] The parties' briefs have not dealt with the pertinent question but we have nevertheless felt obliged to deal with the matter and have concluded that since on the § 103 issue appellants would not today, after *Kuehl*, have to show unexpected properties, there is no basis for requiring such a showing to establish "error" within § 251. It is clear that the patentability of reissue claims is determined by application of the law which exists during the prosecution of the reissue application rather than the law at the date of issuance of the original patent, where there has been a change since then. In Rohm & Haas Co. v. Roberts Chemicals, Inc., 245 F.2d 693 (4th Cir. 1957), the court considered the validity of a reissue patent applied for more than nine years after the original patent issued to add process claims. The court noted two specific provisions of the 1952 Patent Act which were new and that the patentee's belated reissue application was to take advantage of these new provisions when he "made application for the process claims on October 24, 1952, shortly after the passage of the statute." The court said: "The reissued patent was granted on November 24, 1953, after the effective date of the statute, and we think that the validity of the reissue should be construed in light of its provisions."

[8] Similarly in point is Ashley v. Samuel C. Tatum Co., 240 F. 979 (S.D. N.Y.1917), an infringement case upholding the validity of the first design patent ever reissued. The original patent had been obtained when the rules of the Patent Office did not permit a written description of a design in the patent, but only a drawing. The patentee had brought a prior suit on the original patent, which was held valid but not infringed because the alleged infringement, though embodying the patented design, was sufficiently ornamented so as not to resemble the patent drawing. The court noted, however, that the pat-

entee may well have been entitled to more broadly claim the dominant feature of his invention, with or without ornamentation, but had "no such claim, and no written description upon which it could be based * * * possibly solely because the Patent Office refused to allow any written description to be filed * * *." Later, however, the Patent Office rule was changed to provide for a written description in a design patent, and the patentee sought reissue of his patent to add a description of his design and to claim it, not just "as shown," but "as shown and described." He obtained the reissue patent and then sued the original defendant for its infringement. The court upheld the validity of the reissue patent obtained to take advantage of the change in the Patent Office rules and noted the defendant's infringement, but it refused to allow recovery against that defendant because of its intervening rights. See also Moist Cold Refrigerator Co. v. Lou Johnson Co., 217 F.2d 39 (9th Cir. 1954). Accordingly, we see no basis for holding appellants to the case law which may have existed at the time of their original patent and believe that their reissue application may benefit from the change in the law brought about by In re Kuehl.[8] It thus is not necessary to consider whether appellants have established the existence of unexpected properties for the reactions of the appealed claims since their invention has been shown to be unobvious without such a showing.

Summary

The decision of the board affirming the rejection of claims 16, 17, and 19 under 35 U.S.C. §§ 103 and 251 is reversed.

Reversed.

8. It is also possible to look at the so-called "change in the law" here, which comes about from the case law overruling of case law, as merely a later recognition of the fact that the statute had been incorrectly interpreted. Taking this view, one can say the statutory law was always as we interpreted it in *Kuehl*, but had merely been incorrectly applied for a time after In re Saunders. Looked at in this fashion, there really was no change in the law to be taken advantage of by reissue, and the "error" was in not recognizing that *Saunders* was wrong.

MILLER, Judge (concurring).

Although I am in full accord with the result reached by the majority and with most of its opinion, I cannot agree with its oblique criticism of this court's statement in *Wesseler* that in *Byers* the court "ignored the *fact* that the new reissue statute broadened the term 'error' by not limiting it to 'error' that had arisen through 'inadvertence, accident or mistake.'"

In *Byers*, this court agreed with the board's decision, affirming the rejection of claims in a reissue application. The court said: "It is well settled that the deliberate withdrawal or amendment of a claim in order to obtain a patent does not involve inadvertence, accident or mistake and is not an error of the kind which will justify a reissue of the patent including the matter withdrawn."

In *Wesseler*, this court found that, while the appellant had acted "deliberately" in cancelling claims, this was "error without any deceptive intention." It reversed the board's decision affirming the rejection of claims in a reissue application.

Now the majority would revert to *Byers*, saying that the court was correct in its statement that:

> The use of the word "error" . . . instead of the words "inadvertence, accident or mistake," which appeared in the corresponding section . . . of the patent statutes prior to the recodification of 1952, does not involve a substantive change, and the same type of error is necessary to justify a reissue after the enactment of the Patent Act of 1952 . . . .

It cites the Commentary by Federico which, discussing section 251, says:

> There is no indication in the printed record that this change in language

was intended to effect any change in substance and, since the old phrase was usually rather liberally construed, except when the reissue sought to recapture claims cancelled during the prosecution of the original patent, this question would be of minor significance except in connection with the situation mentioned.

However, the Commentary adds:

As to this situation there would be a large body of precedent to overcome, but one commentary urges that there is a liberalization in this respect.

Far more relevant to the determination of legislative intent are the Committee Reports of the House of Representatives and the Senate. These state that "there are a number of changes in substantive statutory law."[1] Giving substance to the changes in language made by section 251, as the court did in *Wesseler*, accords with this statement.

A fundamental principle of statutory interpretation is that a substantial change in language is evidence that a departure from the old law was intended. Johnson v. United States, 225 U.S. 405, 32 S.Ct. 748, 56 L.Ed. 1142 (1912). Here we have a change in the phrase "by inadvertence, accident, or mistake, and without any fraudulent or deceptive intention," to "through error without any deceptive intention." The plain meaning of the new language is that reissue will be allowed for any error, deliberate or not, except where there is "deceptive intention"; whereas, the old language allowed reissue only where there was error consisting of "inadvertence, accident, or mistake," which had been interpreted by "a large body of precedent" *not* to include deliberate cancellation. *In re Byers*, supra. It may be, as the court in *St. Regis Paper Co.* put it, "difficult to imagine an 'error' which would not be encompassed by any of the terms "inadvertence, accident, or mistake'." However, "a large body of precedent" indicates that deliberate error (e.g. cancellation) was *not* encompassed by those terms. Congress is presumed to have had knowledge of the "large body of precedent." See Zemel v. Rusk, 381 U.S. 1, 85 S.Ct. 1271, 14 L. Ed.2d 179 (1965). Thus there is ample basis for the presumption that Congress intended liberalization of the reissue statute. The majority opinion falls far short of rebutting that presumption.

Even assuming, arguendo, that no substantive change was intended, if the language is clear it is conclusive. "There can be no construction when there is nothing to construe." United States v. Hartwell, 73 U.S. (6 Wall.) 385, 396, 18 L.Ed. 830 (1868). Rules of interpretation are resorted to for the purpose of resolving an ambiguity, not for the purpose of creating it. Railroad Comm. of Wisconsin v. Chicago, B & Q R.R. Co., 257 U.S. 563, 589, 42 S.Ct. 232, 66 L.Ed. 371 (1922). This court should follow the plain meaning of the language "through error without any deceptive intention," unless the words are otherwise defined by the statute. If the Congress intended no change but, nevertheless, enacted one, it is for the Congress and not the courts to rectify its "deliberate mistake."

By interpreting "mistake" to include deliberate cancellation, the majority is saying, in effect, that the "well settled" principle referred to in *Byers* was wrong in the first instance. It over-

1. H.R.Rep.No. 1923, 82d Cong. 2d Sess. 5 (1952); S.Rep.No.1979, 82d Cong. 2d Sess. 4 (1952). The House Report (p. 8) and the Senate Report (p. 7) both state that sections 251 and 252 are a "development" of the present statute; that they "make a number of clarifications and a few additions in further development of the subject [of reissue]." The revision notes accompanying each report merely state that "some changes in language" appear in section 251 compared to its predecessor, 35 U.S.C. § 64 (1946 ed.). However, changing the language to cover a patentee "claiming as his own invention or discovery more than he had a right to claim" to "claiming more *or less* than he had a right to claim" (emphasis supplied) obviously was a substantive change. So too the broader language "error without any deceptive intention" represents a substantive change.

comes the "large body of precedent" referred to by Federico—not by recognizing a substantive change enacted by Congress, but by renouncing this court's holding in *Byers* after a lapse of eighteen years.

Application of Eugene S. PENNEBAKER, Jr.
Patent Appeal No. 9210.

United States Court of Customs and Patent Appeals.
May 9, 1974.

Appeal from a decision of the Patent Office Board of Appeals, Serial No. 860,108 affirming rejection for obviousness of application for patent. The Court of Customs and Patent Appeals, Rich, J., held that claims of application for patent for invention relating to a seismic method for determining depth and pressure of highly pressurized (abnormal) formations in sedimentary layers of earth by setting off an explosive charge in earth's surface and detecting seismic or acoustic waves reflected by sedimentary formations with a plurality of linearly arranged geophones were erroneously rejected as obvious to those skilled in art.

Reversed.

Patents ⇐18

Claims of application for patent for invention relating to a seismic method for determining depth and pressure of highly pressurized (abnormal) formations in sedimentary layers of earth by setting off an explosive charge on earth's surface and detecting seismic or acoustic waves reflected by sedimentary formations with a plurality of linearly arranged geophones were erroneously rejected as obvious to those skilled in art. 35 U.S.C.A. § 103.

John S. Schneider, Houston, Tex., attorney of record, for appellant.

Joseph F. Nakamura, Washington, D. C. for the Commissioner of Patents. Jere W. Sears, of counsel.

RICH, Judge.

This appeal is from the decision of the Patent Office Board of Appeals affirming the rejection for obviousness under 35 U.S.C. § 103 of claims 1–3, 7–10, and 14–18 of application serial No. 860,108, filed September 22, 1969, entitled "Method for Prediction of Abnormal Pressures from Routine or Special Seismic Records." We reverse.

The Invention

The invention relates to a seismic method for determining the depth and pressure of highly pressurized (abnormal) formations in sedimentary layers of the earth. The abnormal formations occur as a result of fluids becoming trapped within a relatively impermeable formation such as shale. When such formations are penetrated during drilling, the high pressure can result in a "blowout" and loss of the well unless certain precautions are taken. These precautions involve the setting of casing in the borehole and use of heavier drilling muds with consequential increased costs and slowed drilling rate. By predetermining the depth and location of these formations, the use of these expensive precautions can be reduced. This invention is particularly useful in drilling for oil in unexplored areas (wildcatting).

The invention involves setting off an explosive charge on the earth's surface and detecting seismic or acoustic waves reflected by sedimentary formations with a plurality of linearly-arranged geophones. The geophones are spaced at increasing distances from the charge to measure the two-way travel times of the waves reflected back to the surface by the formations. The average velocity to each reflecting formation is computed from the travel times and plotted as a function of travel time or depth to pro-

APPENDIX 6

In Re Clement

benefit from the accounting services rendered by Decosimo ran to Borden, individually, and to eighteen separate entities to which the Company was either a general partner, managing partner, or managing agent. While it is clear from the record that the personal accounting work done for Borden is not an administrative expense of the Company for which McMillan is liable,[12] the accounting work for the eighteen limited partnerships is a bit more complicated.

[6, 7] Decosimo argues that under Alabama law the Company, as a partner or managing agent of these partnerships, is obligated for the debts of these partnerships.[13] Assuming, without deciding, that such is correct, the avenue for recovery for fees for Decosimo would not be as an administrative expense, but as an unsecured creditor. Accounting fees arising from services performed for other debtors in separate bankruptcy proceedings and arising from work for entities other than the debtor in this case are not fees incurred in the upkeep and maintenance of this debtor's estate and therefore are not to be reimbursed as an administrative expense. The tenuous and incidental benefit Decosimo alleges it provided the Company, without more, is insufficient basis for administrative priority status. *See In re Appliance Store, Inc.*, 181 B.R. 237, 242 (Bankr.W.D.Pa.1995). Rather than give Decosimo a leg up on the other creditors of the Company by granting its fee claims administrative expense priority, we would require Decosimo to proceed against each of the parties for whom the services were rendered. If Decosimo is successful in its suits against these limited partnerships, and if it were found that the Company is liable for Decosimo's fees, then Decosimo would stand as a creditor of the Company, no more and no less. Given the Bankruptcy Code's overriding concern for keeping administrative expenses to a minimum so as to preserve as much of the estate as possible for the creditors, we must carefully review the legitimacy of such claims. *See Otte v. United States*, 419 U.S. 43, 53, 95 S.Ct. 247, 254, 42 L.Ed.2d 212 (1974). Decosimo's fees for work performed for other entities are simply not administrative expenses of the Company for which McMillan is liable under the cash collateral agreement.

IV. CONCLUSION

For the foregoing reasons, we AFFIRM the judgment of the United States District Court for the Northern District of Alabama.

AFFIRMED.

12. There is no written or verbal agreement by either the Company or McMillan to pay for the accounting services rendered to Borden. Decosimo contends that Borden told Decosimo that McMillan would pay for these services. The Company was never invoiced for these services; in fact, Decosimo only invoiced Borden in its search for payment. Consequently, there is no legal basis to allow Decosimo and administrative claim against the Company's estate for these services.

13. Decosimo contends Ala.Code § 10-8-52(2) renders the Company liable for the debts of the various partnerships. § 10-8-52 states: "All partners are liable ... (2) Jointly and severally for all debts and obligations of the partnership, except as may be otherwise provided by law."

KEY NUMBER SYSTEM

In re CLEMENT.

No. 97-1202.

United States Court of Appeals, Federal Circuit.

Dec. 12, 1997.

Rehearing Denied; Suggestion for Rehearing In Banc Declined Feb. 18, 1998.

Patentee filed reissue application in connection with patent claiming method of treating waste paper to remove certain elements. The Board of Patent Appeals and Interferences sustained patent examiner's rejection of claims contained in reissue application, and patentee appealed. The Court of Appeals, Mayer, Circuit Judge, held that: (1) claims in reissue application which were broader than they were narrower in manner directly pertinent to subject matter that patentee surren-

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1. Patents ⇐

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5. Patents ⇐14

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dered throughout prosecution of patent were barred by recapture rule, and (2) defective declaration alone would not invalidate other claims that were not subject to recapture rule.

Affirmed in part and vacated in part.

1. Patents ⇐144

Determining whether applicant for reissue patent has met statutory requirements is question of law, which Court of Appeals reviews de novo, although legal conclusion is based on underlying findings of fact, which Court sustains unless they are clearly erroneous. 35 U.S.C.A. § 251.

2. Patents ⇐136

Attorney's failure to appreciate full scope of invention qualifies as error under statute permitting reissue of defective patents and is correctable by reissue, but deliberate withdrawal or amendment cannot be said to involve inadvertence or mistake contemplated by statute. 35 U.S.C.A. § 251.

3. Patents ⇐141(6)

Recapture rule prevents patentee from regaining through reissue subject matter that patentee surrendered in effort to obtain allowance of original claims, such that claims that are broader than original patent claims in manner directly pertinent to subject matter surrendered during prosecution are impermissible.

4. Patents ⇐141(6)

In applying recapture rule, which prevents patentee from regaining through reissue subject matter that patentee surrendered in effort to obtain allowance of original claims, court first determines whether and in what aspect reissue claims are broader than patent claims and then determines whether broader aspects of reissue claims relate to surrendered subject matter. 35 U.S.C.A. § 251.

5. Patents ⇐141(6)

To determine whether applicant for reissue patent surrendered particular subject matter, Court of Appeals looks to prosecution history for arguments and changes to claims made in effort to overcome prior art rejection. 35 U.S.C.A. § 251.

6. Patents ⇐141(6)

Although recapture rule, which prevents patentee from regaining through reissue subject matter that patentee surrendered in effort to obtain allowance of original claims, does not apply in absence of evidence that applicant's amendment was admission that scope of that claim was not in fact patentable, court may draw inferences from changes in claim scope when other reliable evidence of patentee's intent is not available. 35 U.S.C.A. § 251.

7. Patents ⇐168(2.2)

Deliberately canceling or amending patent claim in effort to overcome reference strongly suggests that applicant admits that scope of claim before cancellation or amendment is unpatentable, but it is not dispositive because other evidence in prosecution history may indicate the contrary.

8. Patents ⇐141(6)

Once court determines that applicant for reissue patent has surrendered subject matter of canceled or amended claim, court then determines whether surrendered subject matter has crept into reissue claim.

9. Patents ⇐141(6, 7)

If scope of reissue claim is same as or broader than that of canceled claim, then patentee is clearly attempting to recapture surrendered subject matter and reissue claim is, therefore, unallowable, but reissue claim narrower in scope escapes recapture rule entirely.

10. Patents ⇐141(6, 7)

If reissue claim is broader in some aspects, but narrower in others, than canceled patent claim then, if reissue claim is as broad as or broader in aspect germane to prior art rejection, but narrower in another aspect completely unrelated to rejection, recapture rule bars claim, but, if reissue claim is narrower in aspect germane to prior art rejection, and broader in aspect unrelated to rejection, recapture rule does not bar claim, but other rejections are possible.

11. Patents ⇐141(6)

Claims in application for reissue patent which were broader than they were narrower in manner directly pertinent to subject matter that patentee surrendered throughout prosecution of patent, which claimed method of treating waste paper to remove certain elements, were barred by recapture rule, regardless of whether reissue claims were broader than canceled claims in manner directly related to alleged error supporting reissue. 35 U.S.C.A. § 251.

12. Patents ⇐140

Claims in application for reissue patent that were not subject to recapture rule would not be invalidated solely by defective reissue declaration. 35 U.S.C.A. § 252.

13. Patents ⇐140

Claims in reissue application that were not different from claims in original patent could not alone support reissue application. 35 U.S.C.A. § 251.

Lawrence M. Green, Wolf, Greenfield & Sacks, P.C., Boston, MA, argued for appellant. With him on the brief was Christopher S. Schultz.

John M. Whealan, Associate Solicitor, Office of the Solicitor, Patent and Trademark Office, Arlington, VA, argued for appellee. With him on the brief were Nancy J. Linck, Solicitor, Albin F. Drost, Deputy Solicitor, and Scott A. Chambers, Associate Solicitor.

Before MAYER, Circuit Judge, SMITH, Senior Circuit Judge, and CLEVENGER, Circuit Judge.

MAYER, Circuit Judge.

Jean-Marie Clement appeals the decision of the United States Board of Patent Appeals and Interferences sustaining the rejection of claims 1–18 and 49–52 in reissue application Serial No. 08/054,951 under 35 U.S.C. § 251 (1994). Because the board correctly applied the recapture rule to bar claims 49–52 and because claims 1–18 alone cannot support the reissue application, we affirm in part and vacate in part.

Background

This case is about U.S. Patent No. 4,780,179 (the '179 patent) issued to Jean-Marie Clement. The '179 patent claims a method for treating waste paper that removes "stickies," such as glues and plastics, under a first set of environmental conditions, before removing inks under a second set of environmental conditions.

The '179 patent issued from application Serial No. 06/822,943 (the '943 application), which was a continuation of application Serial No. 06/482,623 (the '623 application). During prosecution, Clement amended the claims to overcome U.S. Patent No. 4,360,402, issued to Ortner et al. (Ortner), and an article written by Michael Burns entitled "Waste Paper Preparation Plant and Systems," published in the June/August 1973 issue of Paper Technology (Burns). The broadest of the '623 application's claims, original claim 1, recites:

> A method of treating a mixture of printed and contaminated waste paper in order to produce pulps for the use in the manufacture of pulp and paper boards, which method comprises:
>
> (a) forming an aqueous pulp of said waste material at low temperature, low specific mechanical energy, thereby forming a pulpable slurry and releasing the non-ink contaminants from the surface of the paper but without dispersing them inside the fibrous suspension;
>
> (b) separating the non-ink contaminants from the pulp by mechanical separation, without the use of froth floatation or solvent extraction or other process, using conventional screens and centrifugal cleaners and without any further application of strong shear forces to the pulp;
>
> (c) softening of the ink particles vehicles and weakening of their bondings with the surface of the fibres by submitting the pulp at a consistency of more than 15% at the simultaneous actions of (A) high temperature—between 85 and 130° C.—(B) high shear forces and (C) at least one de-inking agent, under alcaline [sic] conditions;
>
> (d) detaching the ink particles from the surface of the fibres and dispersing them

into the fibrous suspension by submitting the pulp to the simultaneous actions of (A) high temperature—between 85 and 130° C.—(B) high shear forces and (C) at least one chemical dispersing agent, under alcaline [sic] conditions;

(e) removing the free ink particles by means of the most appropriate known method and up to the degree of brightness required by the final use of the pulp.

In an effort to overcome Ortner, Clement submitted a preliminary amendment in the '943 application dated January 27, 1986, which replaced original claim 1 with claim 42. Claim 42 is limited to: (1) carrying out step (a) at room temperature; (2) using mechanical energy less than 50 KW.H/Ton in step (a); (3) removing the ink by applying a combination of high temperature between 85 and 130°C, mechanical energy greater than 50 KW.H/Ton, and a de-inking or chemical dispersing agent under alkaline conditions in steps (c) and (d), respectively; and (4) limiting the duration of steps (c) and (d) to between two and ten minutes. In this preliminary amendment, Clement argued that Ortner's process could not apply simultaneously the higher temperature and larger shear force (mechanical energy greater than 50 KW.H/Ton) recited in steps (c) and (d). Clement also argued that using a higher temperature in Ortner's process would prevent the final product from having the necessary brightness.

In response, the examiner withdrew the Ortner reference, but relied on Burns until Clement's amendments dated December 23, 1986, and June 29, 1987, and an examiner's amendment dated May 16, 1988, added the following limitations: (1) steps (a) and (b) remove substantially all the non-ink contaminants including the stickies; (2) steps (c) and (d) include strong alkaline conditions having a pH of at least 9; (3) the brightness of the final pulp in step (f) is at least 59 ISO; and (4) step (b) takes place at room temperature. The table at Appendix A shows claim 42 before the last two amendments. In his December 23, 1986, amendment, Clement specifically argued that Burns fails to disclose the strong alkaline conditions having a pH greater than 9 that he added to steps (c) and (d). In his June 29, 1987, amendment, he continued to traverse the examiner's assertion that Burns discloses removing the stickies at room temperature through the application of mechanical energy lower than 50 KW.H/Ton. The patent issued on October 25, 1988, with claim 42 becoming claim 1, as shown in the table at Appendix B.

On October 18, 1990, Clement filed reissue application Serial No. 07/600,012 (the '012 application). During prosecution of the '012 application, he admitted that he added "very specific process parameters" to issued claim 1 during prosecution of the '943 application "in order to distinguish over the prior art." Clement later abandoned the '012 application in favor of continuation reissue application Serial No. 08/054,951 (the '951 application), presently on appeal. The '951 application includes claims 1–18, which correspond to claims 1–18 of the '179 patent, and claims 49–52, which are admittedly broader than the '179 patent's claims. In his reissue declaration, Clement stated that as a result of his failure to understand the claims and his attorney's failure to appreciate the scope of his invention, claims 1–18 of the '179 patent are unduly limited because "step (a) recites forming the first fibrous suspension at room temperature by applying specific mechanical energy lower than 50 KW. H/Ton." In addition, "the temperature, mechanical energy and pH conditions set forth in steps (c) and (d)" unduly limit claim 1 and claims 2–18, which depend from it. Claim 49 eliminates these limitations and the room temperature limitation in the first claim's step (b). The table at Appendix B compares reissue claim 49 with claim 1 of the '179 patent with differences italicized.

The examiner rejected claims 49–52 under 35 U.S.C. § 251 * for being broadened in a reissue application filed outside the two year statutory period. The examiner also reject-

* Section 251 allows patentees to correct "errors" made during prosecution, such as claiming less than the patentee had a right to claim. A reissue patent may not, however, enlarge the scope of the claims unless the patentee files the reissue application within two years of the grant of the patent.

ed claims 1–18 and 49–52 under section 251 for lacking a basis for reissue because recapture is not an error so correctable. The examiner found the reissue declaration defective under 37 C.F.R. § 1.175 (1997) because it failed not only to mention the error in step (b), but also to explain sufficiently how any of the errors arose. The examiner determined that these defects were not curable because the recapture rule applied. Clement appealed the examiner's final rejection to the United States Board of Patent Appeals and Interferences (the board).

The board determined that Clement filed his broadening reissue application timely. It further found that during prosecution of the '179 patent, Clement added temperature, mechanical energy, and pH limitations to overcome prior art rejections. The board noted that the temperature limitation in step (a) and the temperature and mechanical energy limitations in steps (c) and (d) "were argued by [Clement] to be features not suggested by Ortner or Burns and ... were accepted by the examiner as distinguishing over these references." It concluded that Clement implicitly admitted that "broader claims not restricted to .... [these limitations] were not patentable over the prior art represented by Ortner." The board found that claims 49–52 do not include these limitations and concluded that the reissue claims seek to broaden the patent in a manner directly pertinent to subject matter that Clement deliberately surrendered to overcome prior art rejections. It therefore sustained the rejection of claims 49–52 for failing to comply with 35 U.S.C. § 251, and the rejection of claims 1–18 and 49–52 based on a defective reissue declaration. Clement appeals.

Discussion

[1–3] Determining whether an applicant has met the statutory requirements of 35 U.S.C. § 251 is a question of law, which we review *de novo*. *Mentor Corp. v. Coloplast, Inc.*, 998 F.2d 992, 994, 27 USPQ2d 1521, 1524 (Fed.Cir.1993). This legal conclusion is based on underlying findings of fact, which we sustain unless they are clearly erroneous. *In re Kemps*, 97 F.3d 1427, 1430, 40 USPQ2d 1309, 1312 (Fed.Cir.1996); *Mentor*, 998 F.2d at 994, 27 USPQ2d at 1524. An attorney's failure to appreciate the full scope of the invention qualifies as an error under section 251 and is correctable by reissue. *In re Wilder*, 736 F.2d 1516, 1519, 222 USPQ 369, 370–71 (Fed.Cir.1984). Nevertheless, "deliberate withdrawal or amendment ... cannot be said to involve the inadvertence or mistake contemplated by 35 U.S.C. § 251." *Haliczer v. United States*, 174 Ct.Cl. 507, 356 F.2d 541, 545, 148 USPQ 565, 569 (1966). The recapture rule, therefore, prevents a patentee from regaining through reissue the subject matter that he surrendered in an effort to obtain allowance of the original claims. *See Mentor*, 998 F.2d at 995, 27 USPQ2d at 1524. Under this rule, claims that are "broader than the original patent claims in a manner directly pertinent to the subject matter surrendered during prosecution" are impermissible. *Id.* at 996, 998 F.2d 992, 27 USPQ2d at 1525.

[4] The first step in applying the recapture rule is to determine whether and in what "aspect" the reissue claims are broader than the patent claims. For example, a reissue claim that deletes a limitation or element from the patent claims is broader in that limitation's aspect. Clement argues that the board focused too much on the specific limitations that were omitted from the reissue claims. Although the scope of the claims is the proper inquiry, *In re Richman*, 56 C.C.P.A. 1083, 409 F.2d 269, 274, 161 USPQ 359, 362 (CCPA 1969), claim language, including limitations, defines claim scope. *Altox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1023, 43 USPQ2d 1545, 1548 (Fed.Cir.1997); *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 619, 34 USPQ2d 1816, 1819 (Fed.Cir.1995) ("[T]he language of the claim defines the scope of the protected invention."). Under *Mentor*, courts must determine in which aspects the reissue claim is broader, which includes broadening as a result of an omitted limitation. The board did not err by determining which limitations Clement deleted from the patent claims.

[5] The second step is to determine whether the broader aspects of the reissue

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claims relate to surrendered subject matter. To determine whether an applicant surrendered particular subject matter, we look to the prosecution history for arguments and changes to the claims made in an effort to overcome a prior art rejection. *See Mentor*, 998 F.2d at 995–96, 27 USPQ2d at 1524–25; *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 294–95 (Fed.Cir.1984).

[6, 7] Although the recapture rule does not apply in the absence of evidence that the applicant's amendment was "an admission that the scope of that claim was not in fact patentable," *Seattle Box Co. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 826, 221 USPQ 568, 574 (Fed.Cir.1984), "the court may draw inferences from changes in claim scope when other reliable evidence of the patentee's intent is not available," *Ball*, 729 F.2d at 1436, 221 USPQ at 294. Deliberately canceling or amending a claim in an effort to overcome a reference strongly suggests that the applicant admits that the scope of the claim before the cancellation or amendment is unpatentable, but it is not dispositive because other evidence in the prosecution history may indicate the contrary.** *See Mentor*, 998 F.2d at 995–96, 27 USPQ2d at 1524–25; *Ball*, 729 F.2d at 1438, 221 USPQ at 296; *Seattle Box Co.*, 731 F.2d at 826, 221 USPQ at 574 (declining to apply the recapture rule in the absence of evidence that the applicant's "amendment ... was in any sense an admission that the scope of [the] claim was not patentable"); *Haliczer*, 356 F.2d at 545, 148 USPQ at 569 (acquiescence in the rejection and acceptance of a patent whose claims include the limitation added by the applicant to distinguish the claims from the prior art shows intentional withdrawal of subject matter); *In re Willingham*, 48 C.C.P.A. 727, 282 F.2d 353, 354, 357, 127 USPQ 211, 213, 215 (CCPA 1960) (no intent to surrender where the applicant canceled and replaced a claim without an intervening action by the examiner). Amending a claim "by the inclusion of an additional limitation [has] exactly the same effect as if the claim as originally presented had been canceled and replaced by a new claim including that limitation." *In re Byers*, 43 C.C.P.A. 803, 230 F.2d 451, 455, 109 USPQ 53, 55 (CCPA 1956).

[8, 9] Once we determine that an applicant has surrendered the subject matter of the canceled or amended claim, we then determine whether the surrendered subject matter has crept into the reissue claim. Comparing the reissue claim with the canceled claim is one way to do this. *In re Wadlinger*, 496 F.2d 1200, 1204, 181 USPQ 826, 830 (CCPA 1974); *Richman*, 409 F.2d at 274, 161 USPQ at 362. If the scope of the reissue claim is the same as or broader than that of the canceled claim, then the patentee is clearly attempting to recapture surrendered subject matter and the reissue claim is, therefore, unallowable. *Ball*, 729 F.2d at 1436, 221 USPQ at 295 ("The recapture rule bars the patentee from acquiring, through reissue, claims that are the same or of broader scope than those claims that were canceled from the original application.") (emphasis omitted); *Byers*, 230 F.2d at 456, 109 USPQ at 56. In contrast, a reissue claim narrower in scope escapes the recapture rule entirely. *Ball*, 729 F.2d at 1436, 221 USPQ at 295.

Some reissue claims, however, are broader than the canceled claim in some aspects, but narrower in others. In *Mentor*, for example, the issued claim, which was directed to a condom catheter, recited an adhesive means that was transferred from an outer to an inner surface without turning the condom inside-out. 998 F.2d at 993, 27 USPQ2d at 1523. The issued claim also recited, *inter alia*, that the condom catheter included a "thin cylindrical sheath member of resilient material rolled outwardly upon itself to form consecutively larger rolls...." One canceled claim recited an adhesive means between the rolls, but did not specify that the adhesive was transferred from the outer to the inner surface without turning the condom inside-out. Another canceled claim recited that

** For example, if an applicant amends a broad claim in an effort to distinguish a reference and obtain allowance, but promptly files a continuation application to continue to traverse the prior art rejections, circumstances would suggest that the applicant did not admit that broader claims were not patentable—assuming that the applicant does not ultimately abandon the continuation application because the examiner refuses to withdraw the rejections.

adhesive was transferred from the outer to the inner surface, but did not specify that this operation was done without turning the condom inside-out. The prior art rejections focused on the obviousness of the adhesive means positioned between the rolls and the process of transferring adhesive to the inner surface of the condom.

In making amendments to the claim, the applicant argued that "none of the references relied upon actually showed the *transfer of adhesive* from the outer surface to the inner surface as the sheath is rolled up and then unrolled." *Id.* at 995–96, 998 F.2d 992, 27 USPQ2d at 1524–25 (emphasis in original). The reissue claim eliminated the limitation that adhesive was transferred from the outer to the inner layer, and was, therefore, broader in this aspect. The reissue claim was also narrower than the canceled claim because it recited that the catheter included "a thin, *flexible* cylindrical member of resilient material rolled outwardly upon itself to form *a single roll* . . . ." (Emphasis added). We held that, although the "flexible" and "single roll" limitations made the reissue claim narrower than both the canceled and issued claims, it did not escape the recapture rule because these limitations did not "materially narrow the claim[ ]." *Id.* at 996–97, 27 USPQ2d at 1525–26.

Similarly, in *Ball*, the issued claim recited "a plurality of feedlines" and a "substantially cylindrical conductor." 729 F.2d at 1432–33, 221 USPQ at 291–92. The canceled claim recited "feed means includ[ing] at least one conductive lead," and a "substantially cylindrical conductor." The prosecution history showed that the patentee added the "plurality of feedlines" limitation in an effort to overcome prior art, but the cylindrical configuration limitation was neither added in an effort to overcome a prior art rejection, nor argued to distinguish the claims from a reference. *Id.* The reissue claim included limitations not present in the canceled claims that related to the feed means element, but allowed for multiple feedlines. On balance, the claim was narrower than the canceled claim with respect to the feed means aspect. The reissue claim also deleted the cylindrical configuration limitation, which made the claim broader with respect to the configuration of the conductor. *Id.* at 1437, 729 F.2d 1429, 221 USPQ at 295. We allowed the reissue claim because the patentee was not attempting to recapture surrendered subject matter. *Id.* at 1438, 729 F.2d 1429, 221 USPQ at 296.

[10] In both *Mentor* and *Ball*, the relevance of the prior art rejection to the aspects narrowed in the reissue claim was an important factor in our analysis. From the results and reasoning of those cases, the following principles flow: (1) if the reissue claim is as broad as or broader than the canceled or amended claim in all aspects, the recapture rule bars the claim; (2) if it is narrower in all aspects, the recapture rule does not apply, but other rejections are possible; (3) if the reissue claim is broader in some aspects, but narrower in others, then: (a) if the reissue claim is as broad as or broader in an aspect germane to a prior art rejection, but narrower in another aspect completely unrelated to the rejection, the recapture rule bars the claim; (b) if the reissue claim is narrower in an aspect germane to prior art rejection, and broader in an aspect unrelated to the rejection, the recapture rule does not bar the claim, but other rejections are possible. *Mentor* is an example of (3)(a); *Ball* is an example of (3)(b).

[11] In our case, reissue claim 49 is both broader and narrower in areas relevant to the prior art rejections. Comparing reissue claim 49 with claim 42 before the May 1988 and June 1987, amendments (see the tables at Appendices A and B), we see that claim 49 is narrower in one area, namely, the brightness is "at least 59 ISO in the final pulp." This narrowing relates to a prior art rejection because, during the prosecution of the '179 patent, Clement added this brightness limitation in an effort to overcome Burns. Our comparison also reveals that reissue claim 49 is broader in that it eliminates the room temperature and specific energy limitations of step (a), and the temperature, specific energy, and pH values of steps (c) and (d). This broadening directly relates to several prior art rejections because, in an effort to overcome Ortner, Clement added to step (a) the limitation that it is carried out "at room temperature," and applies "specific

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mechanical energy lower than 50 KW.H/Ton to form a pumpable slurry. . . ." He argued, moreover, that the latter limitation overcame Burns despite the examiner's contention to the contrary. Clement also added to steps (c) and (d) the temperature and specific energy values in an effort to overcome Ortner, and the "strong" alkaline conditions "having a pH of at least 9" limitation in an effort to overcome Burns. Clement admitted, furthermore, that he added these "very specific process parameters . . . in order to distinguish over the prior art." Claim 49 omits each of these limitations.

On balance, reissue claim 49 is broader than it is narrower in a manner directly pertinent to the subject matter that Clement surrendered throughout the prosecution. Even with the additional limitations, claims 50–52 are also broader than they are narrower in a manner directly pertinent to the subject matter that Clement surrendered during prosecution.

We do not address whether the reissue claims in this case are broader than the canceled claims in a manner directly related to the alleged error supporting reissue because we see no dispositive significance in this inquiry. In *Ball*, we said that the recapture rule does not apply when the reissue claim is broader than the canceled claim in a manner unrelated to the alleged error supporting reissue, but did not address whether the recapture rule would apply if the broadening did relate to the alleged error. 729 F.2d at 1438, 221 USPQ at 296. We can envision a scenario in which the patentee intentionally fails to enumerate an error so that he may eliminate a limitation that he argued distinguished the claim from a reference or added in an effort to overcome a reference and claim protection under *Ball*. We, therefore, think *Ball* is limited to its facts: the recapture rule does not apply when the broadening not only relates to an aspect of the claim that was never narrowed to overcome prior art, or argued as distinguishing the claim from the prior art, but also is not materially related to the alleged error. Accordingly, *Ball* does not require us to determine whether the broader aspects of the reissue claims are related to the alleged error supporting reissue.

Clement argues that, although claim 49 is broader than the issued claims, it is materially narrower than original claim 1; therefore, the recapture rule should not apply. He relies on the unsupported assumption that, for purposes of the recapture rule, we should compare the scope of the reissue claims with that of only original claim 1 to determine whether or not the reissue claim is broader in a material way. Clement has chosen original claim 1 as the basis for comparison because, in his view, it does not include limitations enumerated by the board as missing from the reissue claims. These limitations are the room temperature limitation in step (a) and the specific values of the specific energy limitations in steps (c) and (d).

Clement's assumption ignores the board's finding that the reissue claims delete the value of the high temperature and pH limitations in steps (c) and (d) and the room temperature limitation of step (b). It also ignores much of the prosecution history. The prosecution history shows that Clement abandoned the subject matter of claim 42, as it existed before the examiner's amendment dated May 16, 1988, because he allowed the examiner to amend it to obtain allowance and no other evidence suggests that Clement did not intend to abandon it. He also abandoned the subject matter of claim 42, as it existed before his June 29, 1987, amendment, as it existed before his December 23, 1986, amendment, and as it existed in his preliminary amendment. Based on his actions and statements in the prosecution history of the '179 patent and his admission in the history of the '012 application, every time Clement amended his claims, he intentionally omitted or abandoned the claimed subject matter. Furthermore, his argument that we should compare reissue claim 49 with original claim 1 is reminiscent of the patentee's unsuccessful argument in *Byers*. There, the patentee argued that the reissue claims were "intermediate in scope between certain broad claims which were canceled from [the patentee's] original application and the limited claim allowed in the patent." 230 F.2d at 457, 109 USPQ at 57. In response, the court

noted that the "rejection is not based on the cancellation of the broader claims referred to in [the patentee's] brief. . . . The fact that there were other claims whose cancellation did not constitute such a bar is immaterial." *Id.*

We agree with the board's conclusion that the reissue claims are broader than the patent claims in a manner directly pertinent to the subject matter that Clement surrendered during prosecution. Therefore, it correctly applied the recapture rule, and we affirm the board's decision to sustain the examiner's rejection of claims 49–52.

[12] Because we affirm the board's decision on recapture, Clement cannot cure the allegedly defective declaration with respect to claims 49–52. As a result, we do not reach that issue. Because claims 1–18 are not subject to the recapture rule, however, a defective declaration would not, in and of itself, invalidate them. The Commissioner concedes this point and reminds that, because under 35 U.S.C. § 252 (1994) the surrender of the '179 patent does not take effect until the reissue patent issues, "original claims 1–18 continue to exist with their normal presumption of validity," unaffected by the examiner's rejection based on the allegedly defective declaration. We, therefore, vacate the board's decision to the extent that it rejects claims 1–18 because of the allegedly defective declaration.

[13] Claims 1–18 alone cannot support a reissue application. *See In re Keil*, 808 F.2d 830, 830, 1 USPQ2d 1427, 1428 (Fed.Cir. 1987) (Section 251 requires a change in "either the patent specification or claims."); *In re Dien*, 680 F.2d 151, 152 n. 4, 214 USPQ 10, 12 n. 4 (CCPA 1982) ("[I]t goes without saying that reissue of a patent in identical form with the original patent is not a possibility."). The '951 application would fail, therefore, to comply with section 251 even if Clement were to cure the allegedly defective declaration.

Conclusion

Accordingly, the decision of the Board of Patent Appeals and Interferences sustaining the rejection of claims 49–52, and to reject the reissue application is affirmed, and its decision to reject original claims 1–18 is vacated.

COSTS

Each party shall bear its own costs.

AFFIRMED IN PART AND VACATED IN PART.

ATTACHMENT

APPENDIX A

Claim 42
Before Clement's Amendment on 6/29/87

A method of treating a mixture of printed and contaminated waste paper in order to produce pulps for use in the manufacture of paper and paperboards, which method comprises:

(a) forming an aqueous fibrous suspension of said waste paper at room temperature without deinking agents by applying specific mechanical energy lower that [sic] 50 KW. H/Ton to form a pumpable slurry and to release the non-ink contaminants, from the surface of the paper fibers in the absence of deinking agents and without dispersing such non-ink contaminants as finely divided particles throughout the fibrous suspension;

(b) removing the released non-ink contaminants from the fibrous suspension by screening and cleaning;

Claim 42
Before Examiner's Amendment on 5/16/88

A method of treating a mixture of printed and contaminated waste paper in order to produce pulps for use in the manufacture of paper and paperboards, which method comprises:

(a) forming a first aqueous fibrous suspension of said waste paper at room temperature by applying specific mechanical energy lower that [sic] 50 KW.H/Ton to form a pumpable slurry and to release the non-ink contaminants, from the surface of the paper and without dispersing such non-ink contaminants as finely divided particles throughout the fibrous suspension;

(b) removing the non-ink contaminants which have been released without dispersal as finely divided particles from the first fibrous

ATTACHMENT—Continued

Claim 42 Before Clement's Amendment on 6/29/87	Claim 42 Before Examiner's Amendment on 5/16/88
	suspension by screening and cleaning to form a second aqueous fibrous suspension substantially free of non-ink contaminants;
(c) softening the ink vehicles and weakening their binding with the surface of the fibers by submitting the fibrous suspension at a consistency of more than 15% to the simultaneous actions of (A) a high temperature between 85°and 130°C, (B) high shear forces substantially corresponding to a specific mechanical energy of more than 50 KW.H/Ton applied at the said consistency of more than 15% and (C) at least one deinking agent under strong alkaline conditions having a pH preferably greater than 9;	(c) after the step of removing the non-ink contaminants softening the ink vehicles and weakening their binding with the surface of the fibers by submitting the second fibrous suspension at a consistency of more than 15% to the simultaneous actions of (A) a high temperature between 85°and 130°C, (B) high shear forces substantially corresponding to a specific mechanical energy of more than 50 KW.H/Ton applied at the said consistency of more than 15% and (C) at least one deinking agent under strong alkaline conditions having a pH of at least 9; and
(d) detaching the ink particles from the surface of the fibers and dispersing them into the fibrous suspension by submitting the fibrous suspension to the simultaneous actions of (A) high temperature between 85°and 130°C, (B) high shear forces substantially corresponding to a specific mechanical energy of more than 50 KW.H/Ton applied at the said consistency of more that [sic] 15% and (C) at least one chemical dispersing agent, under strong alkaline conditions having a pH preferably greater than 9;	(d) detaching the ink particles from the surface of the fibers and dispersing them into the second fibrous suspension by submitting the second fibrous suspension to the simultaneous actions of (A) high temperature between 85°and 130°C, (B) high shear forces substantially corresponding to a specific mechanical energy of more that [sic] 50 KW. H/Ton applied at the said consistency of more than 15% and (C) at least one chemical dispersing agent, under strong alkaline conditions having a pH of at least 9 whereby higher specific energy inputs and higher temperatures are used to detach the ink particles from the fibers of the second fibrous suspension after removal of the non-ink contaminants than are used on the first fibrous suspension before removal of the non-ink contaminants;
(e) limiting the total duration of the ink softening and detaching steps (c) and (d) to a range between 2 and 10 minutes and	(e) limiting the total duration of the ink softening and detaching steps (c) and (d) to a range between 2 and 10 minutes and
(f) removing the detached ink particles from the fibrous suspension to provide the degree of brightness required in the final product of the pulp.	(f) removing the detached ink particles from the second fibrous suspension to provide the degree of brightness required in the final product of the pulp.

APPENDIX B

Patent Claim 1	Reissue Claim 49
A method of treating a mixture of printed and contaminated waste paper in order to produce a pulp for use in the manufacture of paper and paperboards, said waste paper containing non-ink contaminants including stickies, which method comprises:	A method of treating a mixture of printed and contaminated waste paper in order to produce a pulp for use in the manufacture of paper and paperboards, said waste paper containing non-ink contaminants including stickies, which method comprises:
(a) forming a first aqueous fibrous suspension of said waste paper *at room temperature*	(a) forming a first aqueous fibrous suspension of said waste paper *at a temperature*

ATTACHMENT—Continued

Patent Claim 1	Reissue Claim 49
by applying specific mechanical energy lower that [sic] 50 KW.H/Ton to *form a pumpable slurry and to release substantially all of the non-ink contaminants including the stickies, from the surface of the paper and without dispersing such non-ink contaminants as finely divided particles throughout the fibrous suspension;*	below the melting point of the non-ink contaminants *by applying* specific mechanical energy sufficient to *form a pumpable slurry and to release substantially all of the non-ink contaminants including the stickies, from the surface of the paper and without dispersing such non-ink contaminants as finely divided particles throughout the fibrous suspension;*
(b) removing substantially all of the non-ink contaminants including the stickies, which have been released without dispersal as finely divided particles from the first fibrous suspension by screening and cleaning *at room temperature* to form a second aqueous fibrous suspension substantially free of the non-ink contaminants including the stickies;	(b) removing substantially all of the non-ink contaminants including the stickies, which have been released without dispersal as finely divided particles from the first fibrous suspension by screening and cleaning to form a second aqueous fibrous suspension substantially free of the non-ink contaminants including the stickies;
(c) after the step of removing the non-ink contaminants softening the ink vehicles and weakening their binding with the surface of the fibers by submitting the second fibrous suspension at a consistency of more than 15% to the simultaneous actions of *(A) a high temperature between 85°and 130°C., (B) high shear forces substantially corresponding to a specific mechanical energy of more than 50 KW.H/Ton* applied at the said consistency of more than 15% and *(C) at least one deinking agent under strong alkaline conditions having a pH of at least 9;* and	(c) after the step of removing the non-ink contaminants, *(1)* softening the ink vehicles and weakening their binding with the surface of the fibers, and then *(2)* detaching the ink particles from the surface of the fibers and dispersing the particles into the second fibrous suspension by submitting the second fibrous suspension at a consistency of more than 15% to the simultaneous actions of temperature, pressure, specific energy, and chemical dosing sufficient to insure softening of the ink vehicles,
(d) detaching the ink particles from the surface of the fibers and dispersing them into the second fibrous suspension by submitting the second fibrous suspension to the simultaneous actions of *(A) high temperature between 85°and 130°C., (B) high shear forces substantially corresponding to a specific mechanical energy of more than 50 KW.H/Ton* applied at the said consistency of more that [sic] 15% and *(C) at least one chemical dispersing agent, under strong alkaline conditions having a pH of at least 9* whereby higher specific energy inputs and higher temperatures are used to detach the ink particles from the fibers of the second fibrous suspension after removal of the non-ink contaminants than are used on the first fibrous suspension before removal of the non-ink contaminants;	detachment of the ink particles from the surface of the fibers and dispersion of the detached ink particles into the second fibrous suspension, whereby higher specific energy inputs and higher temperatures are used to detach the ink particles from the fibers of the second fibrous suspension after removal of the non-ink contaminants than are used on the first fibrous suspension before removal of the non-ink contaminants;
(e) limiting the total duration of the ink softening and detaching steps (c) and *(d)* to a range between 2 and 10 minutes and	*(d)* limiting the total duration of step *(c)(1)* and *(c)(2)* to a range between 2 and 10 minutes and
(f) removing the detached ink particles from the second fibrous suspension to provide a brightness of at lesat [sic] 59 ISO [in] the final pulp.	*(e)* removing the detached ink particles from the second fibrous suspension to provide a brightness of at least 59 ISO in the final pulp.

APPENDIX 7

Ball Corp. v. United States

petitioners' motion to dismiss and to strike counts I and II, or in the alternative, to require Ealing to be joined as an involuntary plaintiff. The district court has refused to certify the matter for interlocutory appeal pursuant to 28 U.S.C. § 1292(b).

Petitioners apparently recognize that this court currently has no jurisdiction under 28 U.S.C. § 1292(b) to review interlocutory matters, such as that presented here, even if certified, *Harrington Manufacturing Co. v. Powell Manufacturing Co.*, 709 F.2d 710 (Fed.Cir.1983), or any administrative supervisory authority over any district court under the Federal Courts Improvement Act of 1982, Pub.L. No. 97–164, 96 Stat. 25, as might justify a writ of mandamus under certain circumstances by a regional circuit court. *C.P.C. Partnership v. Nosco Plastics, Inc.*, 719 F.2d 400 (Fed.Cir. 1983).

Accordingly, petitioners are reduced to proceeding under 28 U.S.C. § 1651, the All Writs Act. Nevertheless, we decline to issue the writ sought, finding in the circumstances of this case no clear demonstration of any abuse of discretion by the district court, as in *Mississippi Chemical Corp. v. Swift Agricultural Chemicals Corp.*, 717 F.2d 1374, 219 USPQ 577 (Fed. Cir.1983), or any potential in the actions of that court complained of by petitioners to frustrate the appellate jurisdiction of this court, as was the case in *In re Snap-On Tools Corp.*, 720 F.2d 654 (Fed.Cir.1983). This result makes it unnecessary for us to reach other issues raised in the papers before this court.

IT IS THEREFORE ORDERED that the petition for writ of mandamus is *denied*.

BALL CORPORATION, Appellee,

v.

The UNITED STATES, Appellant.

Appeal No. 84–680.

United States Court of Appeals, Federal Circuit.

March 15, 1984.

Patentee brought action against the Government for alleged unauthorized use of invention. On cross motions for summary judgment, the Claims Court denied both motions. Permission was granted for the Government to take interlocutory appeal. The Court of Appeals, Edward S. Smith, Circuit Judge, held that: (1) construing liberally the term "error" in statute relating to reissue patents, patentee's deliberate cancelation of original single transmission feedline claims in patent for antenna assembly for use in missiles was sufficient error, in that it occurred without deceptive intent, to permit patentee to seek to secure, through reissue, claims narrower in scope than canceled claims in all material respects; (2) fact that the reissue claims were broader in one respect than the original claims did not bar patentee from securing reissue claims; and (3) patentee was not estopped to secure reissue claims.

Affirmed and remanded.

1. Patents ⇐141(2, 3, 6, 7)

Applicability of recapture rule and sufficiency-of-error standard under statute relating to reissue patents turned, in absence of other evidence of patentee's intent in deliberately canceling original claims, on similarity between reissue and canceled claims; narrower reissue claims were allowable, whereas broader reissue claims or reissue claims of same scope as canceled claims were not. 35 U.S.C.A. § 251.

2. Patents ⇐141(2, 6)

Subject matter of canceled original claims and claims presented in reissue application was not alone controlling on issue

of applicability of recapture rule and sufficiency-of-error standard. 35 U.S.C.A. § 251.

3. Patents ⇐141(2, 6)

In determining applicability of recapture rule and sufficiency-of-error standard under statute relating to reissue of patents, focus is not on specific limitations or on elements of claims, but, rather, on respective scope of canceled original claims and reissue claims. 35 U.S.C.A. § 251.

4. Patents ⇐141(2, 7)

Construing liberally the term "error" in statute relating to reissue patents, patentee's deliberate cancelation of original single transmission feedline claims in patent application for antenna assembly for use in missiles was sufficient error, in that it occurred without deceptive intent, to permit patentee to seek to secure, through reissue, claims narrower in scope than canceled claims in all material respects. 35 U.S.C.A. § 251.

See publication Words and Phrases for other judicial constructions and definitions.

5. Patents ⇐141(3)

Fact that reissue claims were broader in one respect than canceled claims was not fatal to patentee's securing the reissue claims, where patentee filed application for reissue within two-year period for broadened reissue specified in statute and broader feature related to aspect of the invention that was not material to alleged error supporting reissue. 35 U.S.C.A. § 251.

6. Patents ⇐134

Reissue is remedial in nature and is based on fundamental principles of equity and fairness. 35 U.S.C.A. § 251.

7. Patents ⇐141(6)

Recapture rule is inherently founded upon equity considerations.

8. Patents ⇐168(2)

Government's "file wrapper estoppel" argument against allowance of reissue claims was unavailing at stage of proceedings not fully addressing validity and infringement issues, but only resolving controlling issue of law relative to those ultimate issues. 35 U.S.C.A. § 251.

Joseph A. Hill, Washington, D.C., for appellant.

Allen Kirkpatrick, Washington, D.C., for appellee.

Before BALDWIN, BENNETT and SMITH, Circuit Judges.

EDWARD S. SMITH, Circuit Judge.

This case presents the question whether a patentee is barred by the recapture rule from securing, through reissue, claims to subject matter previously canceled from the original application. Plaintiff-appellee, Ball Corporation (Ball), brought suit against the Government in the United States Court of Claims under 28 U.S.C. § 1498(a) (1976) for unauthorized use of the invention claimed in U.S. patent No. Re. 29,296 (July 5, 1977) to Krutsinger, et al. (the Krutsinger patent). The Government moved for summary judgment and Ball filed a cross-motion for summary judgment. Both motions were denied.[1] The Government appealed denial of its motion to this court. At the time of that first appeal, the judgment of the trial judge was not final and the issues had not been certified for appeal. In view of the uncertified, interlocutory nature of the appeal at that time, this court on March 30, 1983, issued an order dismissing the appeal for lack of jurisdiction with leave to seek certification and to appeal pursuant to 28 U.S.C. § 1292(d)(2). On November 22, 1983, the trial judge certified the questions. Permission was granted on December 12, 1983, to take interlocutory appeal to this court. The Government again appeals. We con-

1. On October 8, 1982, pursuant to this court's order of October 4, 1982, Judge Colaianni of the U.S. Claims Court entered a judgment denying both parties' motions for summary judgment, corresponding to his earlier report in the case, filed by him as a trial judge of the U.S. Court of Claims on August 23, 1982.

clude that the trial judge properly denied the Government's motion for summary judgment, and we remand the case for trial.

Background

The invention covered by the Krutsinger patent relates to a dual slot antenna assembly [10] (Fig. 1) intended for use on missiles.

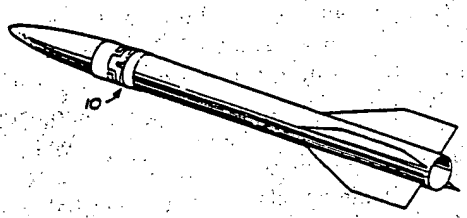

Fig. 1

The antenna (Fig. 2) consists of two thin cylindrical concentric conductors [20, 24] assembled so that they are radially spaced slightly apart to form a cavity [18]. The cavity may be void or may be filled with a dielectric material. The axial length of the conductors is substantially equal to one-half wavelength at the anticipated operating frequency of the antenna. The conductor assembly can be mounted around the outer skin of the vehicle (Fig. 1).

The circumferential edges of the cylindrical conductors define radiation slots [23, 25] (Fig. 3).

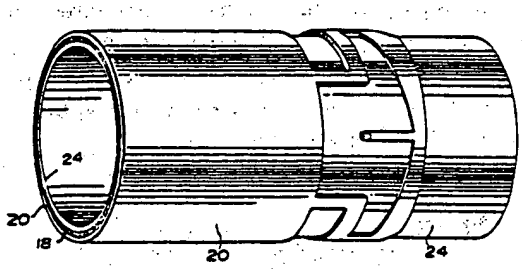

Fig. 2

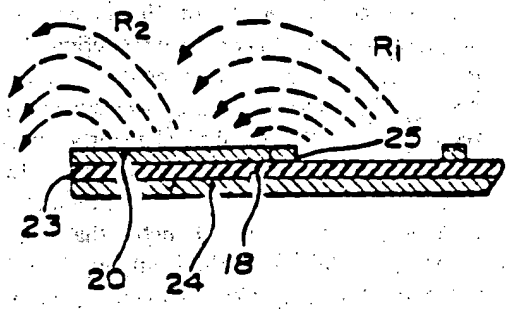

Fig. 3

Because the cylindrical conductors are one-half wavelength long, these radiation slots are, ipso facto, longitudinally spaced one-half wavelength apart at the anticipated operating frequency of the antenna. The radiation slots are excited by signal energy from a source and cooperate to produce an omnidirectional dipole radiation pattern.[2] Due to the one-half wavelength spacing between the radiation slots, the electromagnetic radiation emanating from the

2. Previous missile antennas exhibited signal nulls that made monitoring difficult from a ground tracking station as the missile rolled or changed direction in flight. The claimed antenna exhibits a substantially isotropic radiation pattern which overcomes this problem by eliminating signal nulls.

slots [R_1, R_2] radiates in the same direction and overlaps in an additive manner to provide a stronger radiation pattern.

Signal energy is supplied to the antenna by a connector [70] (Fig. 4).

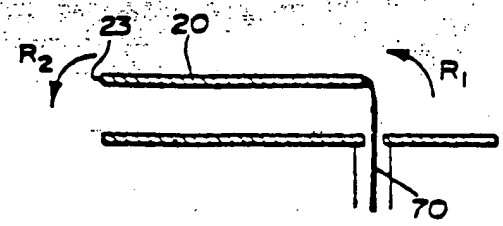

Fig. 4

In the preferred embodiment of the invention, the connection of the inner and outer cylindrical concentric conductive elements to the source is accomplished by means of a single coaxial transmission feedline. It is this feedline element around which the present controversy revolves. In particular, this case involves the number of feedlines to the outer conductor that may be properly claimed in the Krutsinger reissue patent in light of the prosecution history of the original patent application.

The Canceled Claims

Dependent claims 8 and 9 are the only claims of the original application critical to this appeal. Claim 8 includes the single feedline, whereas claim 9 does not. Claim 8 calls for "at least one" conductive lead to be connected to the edge of one of the conductors. Claim 9 requires that "a plurality of leads" be connected to the edge of one of the conductors at circumferentially spaced intervals.

In the first office action on the original application the examiner rejected claims 1–8 and indicated that claims 9 and 10 should be limited to a plurality of feedlines. The claims were amended and, on July 14, 1972, the examiner made his second rejection final. The examiner again suggested the allowability of the plurality of feedlines claims if presented in independent form. The remaining claims were rejected over the newly cited reference, Cork, U.S. patent No. 2,234,234. The Cork patent discloses a single feedline [3] (Fig. 5) and is similar in all other material respects to Krutsinger's antenna.

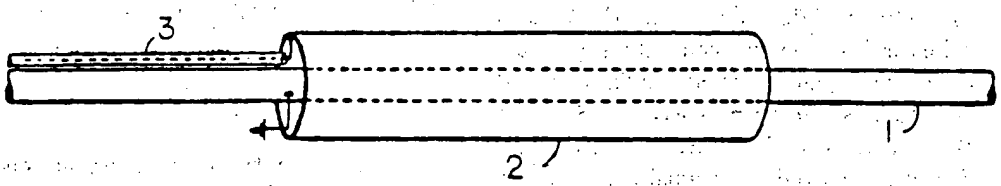

Fig. 5

Following the second office action, Ball added limitations to the claims requiring that a plurality of leads be connected to an edge of the outer conductor. These leads were recited to be spaced-apart at intervals substantially equal to one wavelength at the anticipated operating frequency of the antenna. Ball also canceled claim 7 and dependent claim 8 (the canceled claims), of the original application, which are set forth below:

7. A dual slot antenna assembly comprising: a first substantially cylindrical conductor, the axial length of which is approximately equal to one-half wavelength at the anticipated operating frequency of said assembly; a second substantially cylindrical conductor, the axial length of which is at least equal to the axial length of said first conductor, said second conductor being positioned concentrically within and radially spaced from said first conductor so as to define a pair of circumferential slots spaced one-half wavelength apart at said anticipated operating frequency and providing independent radiation patterns emanating in the same direction; and electrical signal feed means connected with said

conductor for electrically exciting both of said slots.

8. An assembly according to Claim 7 wherein said feed means includes at least one conductive lead which terminates connected to the edge of one of said conductors defining one of said slots.

U.S. patent No. 3,810,183 (the original patent) issued on May 7, 1974, to Ball as assignee, on the basis of the original application, as amended.

Subsequently, Ball decided that it was entitled to claims broad enough to include the single feedline. On July 16, 1975, within the 2-year statutory period for broadened reissue provided in 35 U.S.C. § 251, Ball filed a reissue application. Claims 1–4 of the reissue application comprised the four claims of the original patent. New claims 5–7 were added to the reissue application. Only the new claims, 5–7, directed to the single feedline embodiment, are in issue in this proceeding.[3]

The Alleged Error

In support of its reissue application Ball stated that the original patent was partially inoperative because it claimed less than Ball had a right to claim. Ball identified as error the undue limitation of the claims of the original patent to a plurality of feedlines:

> [T]he unwarranted limited scope of our original patent claims were errors [sic] that arose without any deceptive intention as a result of inadequate and/or ineffective communication with our former patent attorney, * * * and/or as a result of an inadequate understanding on our part of the potential effect of recitations in the original patent claim language under United States laws; * * *[4]

U.S. patent No. Re. 29,296 issued on July 5, 1977, on the basis of the reissue application.

The Reissue Claims

Ball filed an administrative claim with the United States Navy on January 18, 1978, seeking damages and compensation for unauthorized use of, *inter alia*, the invention covered by claims 5, 6, and 7 of U.S. patent No. Re. 29,296. Claims 5, 6, and 7 of the reissue patent are set forth below:

5. A dual slot antenna assembly comprising:

a pair of laterally spaced-apart conductive elements separated with respect to one another by a sheet of dielectric material,

one of said conductive elements being of larger dimensions and underlying the other element and defining an electrical reference or ground surface;

said conductive elements defining a pair of radiation slots between opposing edges of said other element and said reference surface, said radiation slots being longitudinally spaced-apart a predetermined distance approximately equal to one-half wavelength at the anticipated operating frequency of said assembly,

each of which radiation slots emanates radiation therefrom such that the radiation patterns developed are in substantially the same direction;

said radiation slots having a length dimension equal to the entire length of said opposing edges, which length dimension is greater than the spacing between said conductive elements; and

a single electrical signal feed assembly integrally connected with said other conductive element at only one of said opposing edges for electrically exciting both of said radiation slots from a single signal feed junction.

3. *See Haliczer v. United States*, 356 F.2d 541, 544–45, 148 USPQ 565, 568–69 (Ct.Cl.1966) (range of equivalents of original patent claims would not include canceled feature).

4. *See* United States Patent and Trademark Office, *Manual of Patent Examining Procedure* § 1401.08 (1974) (error arising from a lack of understanding or of knowledge by applicant's attorney as to the real invention may be acceptable).

6. An assembly according to claim 5 wherein said conductive elements and said sheet of dielectric material each comprise part of a single sheet of dielectric material metallically cladded on opposite sides thereof.

7. An antenna structure comprising:

an electrically conducting ground surface,

a single layer electrically conducting surface comprising both an r.f. radiator conducting area and an r.f. feedline conducting area integrally connected thereto and formed therewith,

a dielectric sheet disposed between said ground surface and the single layer electrically conducting surface,

said conducting surfaces defining a pair of radiation slots between opposing edges of said r.f. radiator and said ground surface, said radiation slots being longitudinally spaced apart by a predetermined distance approximately equal to one-half wavelength at the anticipated operating frequency of said antenna structure;

each of which radiation slots emanates radiation therefrom such that radiation patterns developed are in substantially the same direction;

said radiation slots having a length dimension equal to the entire length of said opposing edges, which length dimension is greater than the spacing between said surfaces; and

said r.f. feedline being connected to the outside edge of one only of said opposing edges of said r.f. radiation conducting area to at least one predetermined point on the periphery of said radiator conducting area. [Emphasis in original.]

On March 25, 1981, Ball filed a petition in the United States Court of Claims under 28 U.S.C. § 1498 (1976),[5] seeking reasonable and entire compensation for the "infringement" of claims 5, 6, and 7 of U.S. patent No. Re. 29,296. On June 29, 1981, prior to filing an answer, the Government moved for summary judgment. Ball filed a cross-motion for summary judgment.

Judge Colaianni denied both motions. As to the Government's motion, denial of which is on appeal here, the trial judge found that the undisputed evidence of record did not support the Government's arguments; as to Ball's cross-motion, the trial judge found that material issues of fact remained which compelled denial of the motion. Because we agree that neither the recapture rule nor the estoppel doctrine mandate grant of the Government's summary judgment motion, we affirm.

Issues

Two issues are raised in this appeal: (1) whether the error alleged by Ball is sufficient as a matter of law under 35 U.S.C. § 251 (1976) to support reissue; and (2) whether Ball is estopped from securing, through reissue, claims covering the single feedline feature.

The Government contends that Ball's deliberate cancelation of the single feedline claims was not error. That act was taken to avoid a prior art rejection and, in the Government's view, the recapture rule bars Ball from securing similar claims through reissue. The Government also contends

5. 28 U.S.C. § 1498 (1976), *as amended by* The Federal Courts Improvement Act of 1982, Pub.L. No. 97-164, 1982 U.S.CODE CONG. & AD.NEWS (96 Stat.) 25, provides, in pertinent part:

"§ 1498. Patent and copyright cases

"(a) Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Claims Court for the recovery of his reasonable and entire compensation for such use and manufacture.

"For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States."

that the deliberate nature of Ball's acts estops Ball from securing similar claims through reissue. Ball did not appeal the denial of its summary judgment motion but, rather, defends the trial judge's opinion as correct as a matter of law. Resolution of this controversy involves a substantial body of precedent.[6] The parties differ in their interpretation of the law and in their application of it to the facts of this case.

The Recapture Rule

Reissue is not a substitute for Patent Office appeal procedures. Reissue is an extraordinary procedure and must be adequately supported by the circumstances detailed in 35 U.S.C. § 251 (1976)[7] and in the implementing regulations, 37 C.F.R. § 1.175 (1982). The Government asserts that the nature of error that will justify reissue is narrowly circumscribed to ensure that reissue remains the exception and not the rule. Relying on *Edward Miller & Co. v. Bridgeport Brass Co.*,[8] the Government contends that "a mere error of judgment" is not adequate to support reissue; rather the error must be "a real *bona fide* mistake, inadvertently committed."

The 1952 revision of the patent laws made no substantive change in the definition of error under section 251.[9] While deliberate cancellation of a claim cannot ordinarily be considered error,[10] the CCPA has repeatedly held that the deliberate cancellation of claims *may* constitute error, if it occurs without deceptive intent.[11] In *In re Petrow*,[12] the CCPA went so far as to state that error is sufficient where the deliberate cancellation of claims does not amount to an admission that the reissue claims were not patentable at the time the original claims were canceled. Similarly, in *In re Wesseler*,[13] the CCPA stated that error is established where there is no evidence that the appellant intentionally omitted or abandoned the claimed subject mat-

6. The holdings of the U.S. Court of Claims and of the U.S. Court of Customs and Patent Appeals were adopted as precedent in this court in *South Corp. v. United States*, 690 F.2d 1368, 1370, 215 USPQ 657, 658 (Fed.Cir.1982). Both prior courts have ruled on the issues involved in this case. Additionally, several circuit courts have also considered the application of the recapture rule.

7. Section 251 provides in pertinent part:

"§ 251. Reissue of defective patents

"Whenever any patent is, *through error without any deceptive intention*, deemed wholly or partly inoperative or invalid, * * * by reason of the patentee claiming more or less than he had a right to claim in the patent, the Commissioner shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent. * * *

* * * * * *

"No reissued patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent." (Emphasis supplied.)

8. *Edward Miller & Co. v. Bridgeport Brass Co.*, 104 U.S. 350, 355, 26 L.Ed. 783 (1882).

9. *In re Wadlinger*, 496 F.2d 1200, 1206–07, 181 USPQ 826, 831–32 (Cust.Pat. & App.1974); *In re Wesseler*, 367 F.2d 838, 849, 151 USPQ 339, 347 (Cust.Pat. & App.1966); *In re Byers*, 230 F.2d 451, 454, 109 USPQ 53, 55 (Cust.Pat. & App. 1956); *Riley v. Broadway-Hale Stores, Inc.*, 217 F.2d 530, 531 n. 1, 103 USPQ 414, 415 n. 1 (9th Cir.1954). *But see In re Willingham*, 282 F.2d 353, 355, 127 USPQ 211, 214 (Cust.Pat. & App. 1960). "Error" is interpreted in the same manner as under section 64 of the old law, *i.e.*, accident, inadvertence, or mistake.

10. *In re Petrow*, 402 F.2d 485, 487, 159 USPQ 449, 450 (Cust.Pat. & App.1968); *Willingham*, 282 F.2d at 357, 127 USPQ at 215.

11. *See Wadlinger*, 496 F.2d at 1206, 181 USPQ at 831; *Petrow*, 402 F.2d at 487, 159 USPQ at 450; *Wesseler*, 367 F.2d at 849, 151 USPQ at 348; *Willingham*, 282 F.2d at 357, 127 USPQ at 215. *See also Tee-Pak, Inc. v. St. Regis Paper Co.*, 491 F.2d 1193, 1201, 181 USPQ 75, 81 (6th Cir.1974); *Manual of Patent Examining Procedure* § 1401.08.

12. *Petrow*, 402 F.2d at 488, 159 USPQ at 451. *See also Wesseler*, 367 F.2d at 846, 151 USPQ at 344–46; *Willingham*, 282 F.2d at 357, 127 USPQ at 215–16; *Tee-Pak*, 491 F.2d at 1201, 181 USPQ at 81.

13. *Wesseler*, 367 F.2d at 850, 151 USPQ at 349. *See also Riley*, 217 F.2d at 532, 103 USPQ at 415.

ter. Thus, the CCPA has construed the term error under section 251 broadly.[14]

The Ninth Circuit employed a more rigid standard in *Riley v. Broadway-Hale Stores, Inc.*[15] stating: "when the chief element added by reissue has been abandoned while seeking the original patent, the reissue is void." The trial judge sought to determine whether Ball had made a deliberate judgment that claims of substantially the same scope as the new reissue claims would have been unpatentable. The Government, arguing from *Riley*, submits that the trial judge's approach loses sight of the feature given up by a patentee in order to secure the original patent. We decline to adopt the rigid standard applied in *Riley*, in favor of the more liberal approach taken by the CCPA. *Petrow* clearly establishes the vitality of the standard employed by the trial judge under this court's precedent.

Further, the Government argues that we need not reach the issue of claim scope because the sufficiency of error is a threshold issue. While claim scope is no oracle on intent, the Government fails to apprehend its role. Rarely is evidence of the patentee's intent in canceling a claim presented. Thus, the court may draw inferences from changes in claim scope when other reliable evidence of the patentee's intent is not available. Claim scope is not the lodestar of reissue. Rather, the court's reliance on that indicator in the case law appears to be born of practical necessity as the only available reliable evidence.

14. *Wadlinger*, 496 F.2d at 1207–08, 181 USPQ at 832; *In re Richman*, 409 F.2d 269, 273–75, 161 USPQ 359, 362–63 (CCPA 1969); *Wesseler*, 367 F.2d at 849, 151 USPQ at 347–48; *Willingham*, 282 F.2d at 355–56, 127 USPQ at 214. *But see In re Wadsworth*, 107 F.2d 596, 43 USPQ 460 (CCPA 1939).

15. *Riley*, 217 F.2d at 532, 103 USPQ at 415.

16. *Haliczer*, 356 F.2d 541, 148 USPQ 565.

17. *Id.* at 545, 148 USPQ at 569 (bars reissue claims of same scope); *Byers*, 230 F.2d at 455–57, 109 USPQ at 56–57 (bars reissue claims that are of broader scope than canceled claims); *Wadsworth*, 107 F.2d at 599, 43 USPQ at 463 (bars reissue claims of similar scope).

The Government relies heavily on *Haliczer v. United States*,[16] which also involved a suit under 28 U.S.C. § 1498. The Court of Claims in that case held the reissue claims invalid because the patentee sought to acquire through reissue the *same* claims that had earlier been canceled from the original application. The recapture rule bars the patentee from acquiring, through reissue, claims that are of the *same* or of *broader scope* than those claims that were canceled from the original application.[17] On the other hand, the patentee is free to acquire, through reissue, claims that are *narrower* in scope than the canceled claims.[18] If the reissue claims are narrower than the canceled claims, yet broader than the original patent claims, reissue must be sought within 2 years after grant of the original patent.

[1–3] Thus, the applicability of the recapture rule and the sufficiency of error under section 251 turn in this case, in the absence of other evidence of the patentee's intent, on the similarity between the reissue and the canceled claims. Narrower reissue claims are allowable; broader reissue claims or reissue claims of the same scope as the canceled claims are not.[19] The subject matter of the claims is not alone controlling.[20] Similarly, the focus is not, as the Government contends, on the specific limitations or on the elements of the claims but, rather, on the *scope* of the claims.[21]

18. *Wadlinger*, 496 F.2d at 1204, 181 USPQ at 830; *Petrow*, 402 F.2d at 488, 159 USPQ at 451; *Wesseler*, 367 F.2d at 846–47, 151 USPQ at 346; *Willingham*, 282 F.2d at 356, 127 USPQ at 215.

19. If reissue is sought where claims have not been previously canceled, analysis becomes more difficult. In that case relative claim scope is not available to illuminate the alleged error. We are not faced with that situation in this proceeding.

20. *Petrow*, 402 F.2d at 488, 159 USPQ at 451.

21. *Richman*, 409 F.2d at 274–75, 161 USPQ at 362–63. *See also Wadsworth*, 107 F.2d 596, 43 USPQ 460 (analysis turns on substantiality of similarity of reissue to canceled claims).

Ball's Reissue Claims

[4] The trial judge required the Government to establish that the applicant has made a deliberate decision that the canceled claims are unpatentable. The Government argues that that standard is not correct because it loses sight of the *feature* that the patentee gave up during prosecution of the original application. We find the Government's argument entirely unpersuasive. The proper focus is on the *scope* of the claims, not on the individual *feature* or *element* purportedly given up during prosecution of the original application. The trial judge quite properly focused on the scope of the claims and we find no error in this respect. He determined that the reissue claims were intermediate in scope—broader than the claims of the original patent yet narrower than the canceled claims.

The alleged inadequacy of Ball's proffered error is not as clear as the Government contends. The error supporting reissue submitted by Ball comports with the statute and regulations. Further, we fail to perceive the "inconsistency" of Ball's position as asserted by the Government.

The canceled claims, claims 7 and 8,[22] define the invention quite broadly. Canceled claim 8 requires feed means including at least one conductive lead. The reissue claims,[23] in contrast, include limitations not present in the canceled claims: the cavity is filled with a dielectric material; and an electrical signal feed assembly replaces the feed means of the canceled claims. The electrical signal feed assembly (Fig. 6) is a network of leads with a single coaxial feedline to that network. The network consists of a plurality of thin ribbon-like conductive leads.

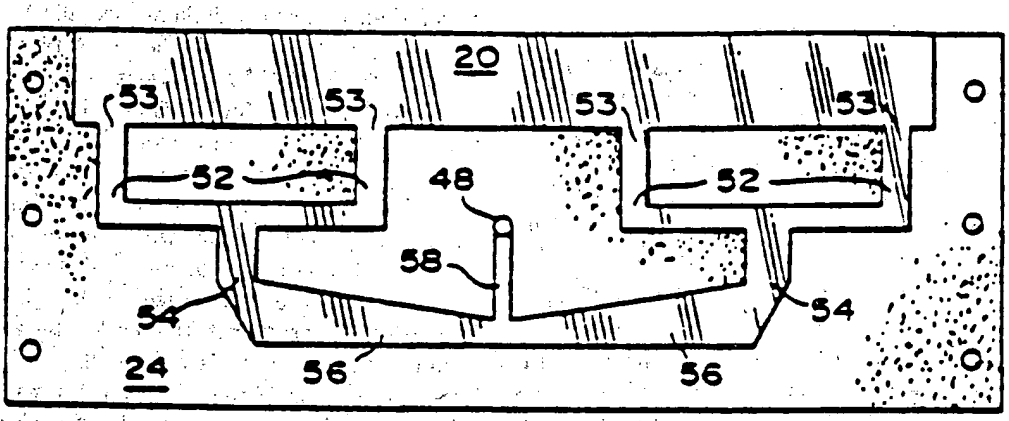

Fig. 6

Feed points [53] to the outer conductor are one wavelength apart at the anticipated operating frequency of the antenna. The leads of this network [52, 54, 56, 58] are dimensioned to provide continuous impedance matching between the cavity and the single coaxial feedline [70], which feeds into the assembly at the aperture [48]. The signal feed assembly is more limited than the "at least one" feed means limitation of canceled claim 8.

[5] The reissue claims are, however, broader in one respect. The canceled claims are limited to an antenna of cylindrical configuration, whereas the reissue claims are not so limited. We are aware of the principle that a claim that is broader in any respect is considered to be broader

22. *See supra* "The Canceled Claims."

23. *See supra* "The Reissue Claims."

Pursuant to section 251, broadened reissue must be sought within 2 years after issuance of the original patent. The CCPA, in *In re Rogoff*,[25] noted that section 251

> contains no exceptions or qualifications as to time or extent of enlargement. The sole issue, therefore, is whether the claims on appeal enlarge, i.e., broaden, the patent claim.
>
> It is well settled that a claim is broadened, so far as the question of right to reissue is concerned, if it is so changed as to bring within its scope any structure which was not within the scope of the original claim. In other words, a claim is broadened if it is broader in any respect than the original claim, even though it may be narrowed in other respects. * *

Thus, the principle that a claim is broadened if it is broader in any respect than the original claim serves to effect the bar of section 251 against reissue filed later than 2 years after issuance of the original patent. In this case, Ball filed its application for reissue within the 2-year period for broadened reissue specified in section 251.

We know of no authority applying the above rule to reissue claims relative to the scope of canceled claims within the 2-year period for broadened reissue. Nor do we perceive the wisdom of such extension in this case. The rule is rigid and properly so in that it effects an express statutory limitation on broadened reissue. The recapture rule, however, is based on equitable principles. The rigidity of the broader-in-any-respect rule makes it inappropriate in the estoppel situation presented in this appeal.

re Price, 302 F.2d 741, 741–42, 133 USPQ 527, 528 (Cust. & Pat.App.1962) (3 years after issue); *In re Ruth*, 278 F.2d 729, 730, 126 USPQ 155, 156 (Cust. & Pat.App.1960) (4 years after issue).

25. *In re Rogoff*, 261 F.2d 601, 603–04, 120 USPQ 185, 186 (Cust. & Pat.App.1958).

Hence, we decline to apply that rule here, where the broader feature relates to an aspect of the invention that is not material to the alleged error supporting reissue. In *Willingham*, the CCPA reversed the rejection of a claim that was narrower than the canceled claim as to one element, although broader as to another element. "The extent to which [deliberate cancellation of a claim from the original application] may also prevent [a patentee] from obtaining other claims differing in form or substance from that cancelled necessarily depends upon the facts in each case and particularly on the reasons for the cancellation." [26] Accordingly, we hold that the reissue claims are not substantially identical in scope to the canceled claims.

As noted *supra*, there is widespread agreement that reissue claims that are narrower than the canceled claims are allowable. In *In re Wadlinger*,[27] the CCPA faced a situation in which the reissue claims were, as the trial judge found here, of "different" scope from the canceled claims. While both the reissue and canceled claims were directed to the same process in *Wadlinger*, the canceled claims were considered broader, resulting in claims of different scope. The reissue claims were held valid. Similarly, we find that the non-material, broader aspects of Ball's reissue claims do not deprive them of their fundamental narrowness of scope relative to the canceled claims. Thus, the reissue claims are sufficiently narrower than the canceled claims to avoid the effect of the recapture rule.

Estoppel

[6, 7] The Government also argues that Ball is estopped to secure the reissue claims. We do not consider this argument as stating an independent ground for relief.

26. *Willingham*, 282 F.2d at 357, 127 USPQ at 215.

27. *Wadlinger*, 496 F.2d at 1205–06, 181 USPQ at 830–31.

The recapture rule is a creature of equity and it embodies the estoppel notions which the Government now urges upon us.[28] We have already resolved this issue against the Government.

[8] We agree with the patentee that the Government's "file wrapper estoppel" argument is equally unavailing. The doctrine of estoppel based on the prosecution history is a corollary to the doctrine of equivalents, a tool in the analysis of infringement. The parties are before this court purely on a controlling issue of law relative to the validity of the reissue claims being asserted by Ball. There has not yet been a full trial on the issue of infringement, let alone on the validity of the reissue claims.[29] The Government's estoppel argument does no more than restate the basic equitable principles underlying the recapture rule.

Conclusion

The trial judge properly articulated the law governing reissue. While broader in scope than the original claims, the reissue claims are narrower in scope than the canceled claims. The error supporting reissue appears to be sufficient. On the basis of the facts before us and the reasons given for the cancellation of the claims from the original application, we cannot find, as a matter of law, that Ball is barred from securing reissue claims drawn to the single feedline embodiment of its invention. The case is remanded to the Claims Court for further proceedings consistent with this opinion.

AFFIRMED AND REMANDED.

28. Reissue is remedial in nature and is based on fundamental principles of equity and fairness. The recapture rule is inherently founded on similar considerations of equity, providing guidance in the application of the law governing reissue. *See Wesseler*, 367 F.2d at 848, 151 USPQ at 347; *Willingham*, 282 F.2d at 354–55, 127 USPQ at 214.

29. The Government apparently misconstrues *Haliczer* in this respect. In *Haliczer*, the court determined that the doctrine of equivalents would require that the *original* claims, carried over into the reissue patent, would not be entitled to the range of equivalents that were purposely surrendered during prosecution of the *original* patent. This is based on an estoppel notion born of the inconsistency of arguing that the *original* claims cover that which was given up during the prosecution of the original patent. The *reissue* claims, not the original claims, are in issue here and the Government's reasoning is, therefore, inapposite. There is no inconsistency in arguing the broadened scope of the reissue claims and, thus, no estoppel.

APPENDIX 8

Pannu v. Storz

summary judgment in favor of the government and thereby sustaining BJA's denial of Ms. Yanco's claim for death benefits under the Benefits Act is

AFFIRMED.

COSTS

Each party shall bear its own costs.

Jaswant S. PANNU and Jaswant S. Pannu, M.D., P.A., Plaintiffs–Appellants,

v.

STORZ INSTRUMENTS, INC., Defendant–Appellee.

No. 00–1482.

United States Court of Appeals, Federal Circuit.

July 25, 2001.

Owner of reissued patent for intraocular lens brought patent infringement action against competitor, and competitor counterclaimed for a declaratory judgment that patent was invalid. The District Court, 106 F.Supp.2d 1304, William P. Dimitrouleas, J., granted competitor summary judgment on counterclaim, on grounds that patent was invalid under recapture rule. Patentee appealed. The Court of Appeals, Mayer, Chief Judge, held that: (1) reissue claim broadened original claim; (2) reissue claim related to subject matter surrendered during prosecution of original patent; (3) reissued claims were not narrowed in any material respect compared with their broadening from original patent claims; and (4) under recapture rule, patentee was estopped by prosecution history from recapturing limitation in original patent claim.

Affirmed.

1. Federal Courts ⇐776

A district court's grant of summary judgment is reviewed de novo on appeal.

2. Patents ⇐314(5), 324.5

Determining whether the claims of a reissued patent violate statute governing reissue of defective patents is a question of law, which appellate courts review de novo. 35 U.S.C.A. § 251.

3. Patents ⇐324.55(3.1)

In determining whether the claims of a reissued patent violate statute governing reissue of defective patents, the legal conclusion can involve underlying findings of fact, which are reviewed for substantial evidence. 35 U.S.C.A. § 251.

4. Federal Civil Procedure ⇐2470, 2470.4

Summary judgment is appropriate only when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law.

5. Patents ⇐314(5), 323.2(2)

Patent claim construction is a purely legal question, and therefore, comparison of claims in origina
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6. Patents ⇐141(6

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7. Patents ⇐141(6

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8. Patents ⇐141(6)

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of claims in original patent and a reissue patent is a purely legal question appropriate for summary judgment.

6. Patents ⇐141(6)

The "recapture rule" prevents a patentee from regaining through reissue the subject matter that he surrendered in an effort to obtain allowance of the original claims. 35 U.S.C.A. § 251.

See publication Words and Phrases for other judicial constructions and definitions.

7. Patents ⇐141(6)

Under the recapture rule, reissued claims that are broader than the original patent's claims in a manner directly pertinent to the subject matter surrendered during prosecution are impermissible. 35 U.S.C.A. § 251.

8. Patents ⇐141(6)

Application of the recapture rule is a three-step process to determine: (1) whether and in what aspect the reissue claims are broader than the patent claims; (2) whether the broader aspects of the reissued claim relate to surrendered subject matter; and (3) whether the reissued claims were materially narrowed in other respects to avoid the recapture rule. 35 U.S.C.A. § 251.

9. Patents ⇐141(4)

Patentee's reissue claim necessarily involved broadening of original claim, and thus patentee's reissue patent was invalid under the recapture rule, where patentee admitted in reissue oath that claim was unnecessarily narrowed in original patent, and reissue claim eliminated limitation in original patent on shape of haptics for patented intraocular lens. 35 U.S.C.A. § 251.

10. Patents ⇐141(3.1)

A reissue claim that does not include a limitation present in the original patent claims is broader in that respect. 35 U.S.C.A. § 251.

11. Patents ⇐141(4)

Reissued claim related to subject matter surrendered during prosecution of original patent, and thus patentee's reissue patent was invalid under the recapture rule, where original claim limited patent to particular shape of haptics for intraocular lens, and shape of haptics was broadened during reissue. 35 U.S.C.A. § 251.

12. Patents ⇐141(6)

Reissued claims were not narrowed in any material respect compared with their broadening from original patent claims, as would avoid invalidation of reissue patent under the recapture rule, where narrowing aspect of claim on reissue was related to positioning and dimensions of snag resistant means, rather than shape of haptics for intraocular lens, which was broadened claim. 35 U.S.C.A. § 251.

13. Patents ⇐141(6)

Patentee was estopped by prosecution history from recapturing limitation in original patent claim he added to overcome prior art rejections, by way of reissue patent, where reissue claims were broader than original patent claims in a manner directly pertinent to subject matter surrendered during prosecution. 35 U.S.C.A. § 251.

14. Patents ⇐141(6)

If the patentee is seeking to recover subject matter that had been surrendered during the initial prosecution, flexibility of analysis is eliminated in determining

whether recapture rule is avoided on grounds reissued claims are materially narrowed compared with their broadening, for the prosecution history establishes the substantiality of the change and estops its recapture. 35 U.S.C.A. § 251.

Michael C. Cesarano, Akerman, Senterfitt & Eidson, P.A., of Miami, FL, argued for plaintiffs-appellants.

Edward W. Remus, McAndrews, Held & Malloy, Ltd., of Chicago, IL, argued for defendant-appellee. With him on the brief was Jonathan R. Sick. Of counsel on the brief were Craig E. Larson, Bausch & Lomb, Incorporated, of Rochester, NY; and Rita D. Vacca, Bausch & Lomb Surgical, Inc., of St. Louis, MO.

Before MAYER, Chief Judge, FRIEDMAN, Senior Circuit Judge, and RADER, Circuit Judge.

MAYER, Chief Judge.

Jaswant S. Pannu and Jaswant S. Pannu, M.D., P.A. (collectively Pannu) appeal the judgment of the United States District Court for the Southern District of Florida, *Pannu v. Storz Instruments, Inc.*, 106 F.Supp.2d 1304 (S.D.Fla.2000), granting summary judgment for Storz Instruments, Inc. (Storz) that U.S. Patent No. Re 32,525 is invalid under 35 U.S.C. § 251, the recapture rule. Because the reissued patent improperly broadened claims in a manner directly pertinent to subject matter surrendered during prosecution, we affirm.

1. The eye is considered to have two chambers separated by the iris. The anterior chamber lies between the back surface of the cornea and front surface of the iris. Attorneys' Dictionary of Medicine and Word Finder A–280 (1995). The posterior chamber is the space between the back surface of the iris and the front surface of the crystalline lens. *Id.* at P–280.

Background

In 1980, Pannu filed a patent application for an artificial intraocular lens, S/N 136,243 ('243 application). An intraocular lens is an artificial plastic lens that may be implanted in an eye to replace a natural lens. The '243 application disclosed a round lens called an "optic" that focuses light on the retina, and two or more elements called "haptics" that are attached to the optic and contact internal tissue in the eye for the purpose of positioning and securing the optic. The haptics in Pannu's application included "snag resistant" discs at the end. In 1981, Pannu filed a continuation-in-part application, S/N 261,953 ('953 application), based on the original '243 application. The '953 application added new matter, claiming a lens in which the haptics are "integrally molded" to the lens body, and the lens could be placed in either the anterior or posterior chamber of the eye.[1]

Independent claim 1 of the '953 application reads as follows:

A posterior chamber intraocular lens comprising:

a lens having a width and a thickness;

a retention loop including a flexible strand having a width and a thickness and such strand is joined at one end to the lens and has an opposite free end;

and a snag resistant disc joined to the flexible strand's free end;

said snag resistant disc having a width which is at least 3 times greater than the thickness of the disc, at least 3 times

greater than the width of the flexible strand, and at least ⅛ as great as the width of the lens for smoothly guiding the free end of the flexible strand across an inner edge of an iris when moving said strand into and out of a posterior chamber of an eye;

said snag resistant disc lying in a plane sufficiently close to a plane of the lens so that both the disc and lens can fit into a posterior chamber behind an eye's iris.

The examiner rejected claims 1–14 as obvious under 35 U.S.C. § 103 in light of four prior art references: U.S. Patent No. 4,159,546 (Shearing patent), a publication showing the "Lindstrom Centrex" lens, U.S. Patent No. 4,249,271 (Poler patent), and U.S. Patent No. 4,092,743 (Kelman patent). In response, Pannu filed a supplemental amendment that cancelled claims 1–7 and 10–14, added new claims 16–22, and modified claims 8 and 9 to be dependent upon claim 16. Independent claim 16 reads as follows:

An intraocular lens comprising:

a lens body;

at least two flexible positioning and supporting elements integrally formed with said lens body and extending from the periphery of said lens body;

said elements defining a continuous, substantially circular arc having a diameter greater than the diameter of said lens body, said arc curved toward said lens circumference; and

snag resistant means integrally formed on the free end of said elements for smoothly guiding the lens across eye tissue when implanting the lens.

Pannu raised six arguments for the patentability of claim 16 over the four prior art references, including the distinction of "a continuous substantially circular arc having a diameter greater than the diameter of the lens body . . . which significantly enhance the easy insertibility of applicant's lens and significantly reduce any possibility of snagging delicate eye tissue." The examiner accepted Pannu's arguments, and allowed claim 16 subject to minor amendments to set forth precisely the structural details of the haptics. Claim 16 issued as claim 1 of U.S. Patent No. 4,435,855 ('855 patent) and reads as follows:

An intraocular lens comprising:

a lens body;

at least two spaced flexible positioning and supporting elements integrally formed with said lens body as a one piece construction and extending radially outward from the periphery of said lens body;

said elements defining a continuous, substantially circular arc having a diameter greater than the diameter of said lens body, said arc curved toward said lens circumference and terminating in a free end spaced from said periphery; and

snag resistant means integrally formed on the free end of said elements for smoothly guiding and positioning the lens across contacted eye tissue when implanting the lens,

said snag resistant means having an uninterrupted continuously smoothly curved outer periphery which merges with said free end and is substantially greater in size than the width of said flexible elements.

In 1985, Pannu filed an application for reissue of the '855 patent. The supplemental reissue oath stated that Pannu "unduly and without deceptive intent narrowed the claims beyond what was neces-

sitated by the applied prior art by describing the shape of the outwardly extending elements as defining 'a continuous, substantially circular arc having a diameter greater than the diameter of the lens body.'" The examiner allowed Pannu to delete "defining a continuous, substantially circular arc having a diameter greater than the diameter of said lens body, said arc curved toward said lens circumference and terminating in a free end" from claim 1. However, the examiner required Pannu to insert additional limitations into the last section of the claim. The last section of claim 1 reads as follows with italics indicating additions and bracketing indicating deletions:

> said snag resistant means having an uninterrupted, continuously smoothly curved outer periphery which merges with said free end and is [substantially] at least three times greater in [size] width than the width of said flexible elements, said snag resistant elements and said positioning and supporting elements being substantially coplanar.

The '855 patent reissued as U.S. Patent No. Re 32,525 ('525 reissue).

Pannu filed suit against Storz, alleging that intraocular lenses sold by Storz infringed the '525 reissue. Storz filed a counterclaim seeking a declaratory judgment of patent invalidity, and moved for summary judgment that the '525 reissue improperly recaptures subject matter Pannu surrendered in obtaining allowance of claim 1 of the '855 patent. The court granted Storz's motion for summary judgment of invalidity and Pannu appeals.

Discussion

[1–5] "We review a district court's grant of summary judgment de novo." *Vanmoor v. Wal–Mart Stores, Inc.*, 201 F.3d 1363, 1365, 53 USPQ2d 1377, 1378 (Fed.Cir.2000). Determining whether the claims of a reissued patent violate 35 U.S.C. § 251 is a question of law, which we review *de novo*. *In re Clement*, 131 F.3d 1464, 1468, 45 USPQ2d 1161, 1163 (Fed.Cir.1997); *Mentor Corp. v. Coloplast, Inc.*, 998 F.2d 992, 995, 27 USPQ2d 1521, 1524 (Fed.Cir.1993). This legal conclusion can involve underlying findings of fact, which are reviewed for substantial evidence. *Hester Indus., Inc. v. Stein, Inc.*, 142 F.3d 1472, 1479, 46 USPQ2d 1641, 1647 (Fed.Cir.1998); *Mentor*, 998 F.2d at 994, 27 USPQ2d at 1524 (citing *Ball Corp. v. United States*, 729 F.2d 1429, 1439, 221 USPQ 289, 297 (Fed.Cir.1984)). However, summary judgment is appropriate only when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. *Vanmoor*, 201 F.3d at 1365, 53 USPQ2d at 1378. The underlying facts in this case are taken directly from the prosecution file histories and the claims of the '855 patent and the '525 reissue, and are not disputed. *See Hester*, 142 F.3d at 1484, 46 USPQ2d at 1651. Claim construction is a purely legal question, *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1456, 46 USPQ2d 1169, 1174 (Fed.Cir.1998) (en banc), and therefore, comparison of the claims of the '855 patent and the '525 reissue is a purely legal question appropriate for summary judgment, *Westvaco Corp. v. Int'l Paper Co.*, 991 F.2d 735, 741, 26 USPQ2d 1353, 1358 (Fed.Cir.1993) ("A determination of whether the scope of a reissue claim is identical with the scope of the original claim is a question of law, which we review de novo.").

[6–8] The recapture rule "prevents a patentee from regaining through reissue

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the subject matter that he surrendered in an effort to obtain allowance of the original claims." *Clement*, 131 F.3d at 1468, 45 USPQ2d at 1164. Reissued claims that are broader than the original patent's claims in a manner directly pertinent to the subject matter surrendered during prosecution are impermissible. *Id.* (quoting *Mentor*, 998 F.2d at 996, 27 USPQ2d at 1525). Application of the recapture rule is a three-step process. The first step is to "determine whether and in what 'aspect' the reissue claims are broader than the patent claims." *Id.* "The second step is to determine whether the broader aspects of the reissued claim related to surrendered subject matter." *Id.* Finally, the court must determine whether the reissued claims were materially narrowed in other respects to avoid the recapture rule. *Hester*, 142 F.3d at 1482–83, 46 USPQ2d at 1649–50; *Clement*, 131 F.3d at 1470, 45 USPQ2d at 1165.

[9, 10] With respect to the shape of the haptics, claim 1 of the '525 reissue is broader than claim 1 of the original '855 patent. Claim 1 of the '855 patent limited the haptics to "a continuous, substantially circular arc having a diameter greater than the diameter of said lens body, said arc curved toward said lens circumference." Claim 1 of the '525 reissue eliminated this limitation on the shape of the haptics. "A reissue claim that does not include a limitation present in the original patent claims is broader in that respect." *Hester*, 142 F.3d at 1480, 46 USPQ2d at 1648. In addition, Pannu's reissue oath admitted that he unnecessarily narrowed the scope of the claim with respect to the shape of the haptics. He stated that "the [haptics] may actually be of any shape as long as the elements terminate in a free end having snag resistant means as now recited in claim 1." Correction of Pannu's unnecessary narrowing of claim 1 must involve a corresponding broadening of the reissued claim.

[11] Pannu argues that even if the reissued claim is broader, it did not relate to subject matter surrendered during prosecution. This argument is without merit. As originally filed, none of the claims in the '953 application limited the shape of the haptics. The examiner rejected claims 1–14 as obvious. In response to the rejection, Pannu filed a supplemental amendment canceling claim 1 and adding new independent claim 16. Claim 16 described the haptics as "defining a continuous, substantially circular arc having a diameter greater than the diameter of said lens body, said arc curved toward said lens circumference." Pannu argued to the examiner, "no such particular shape is disclosed by the lenses of either Shearing or Lindstrom. In fact, Shearing teaches away from the concept of a continuous substantially circular arc supporting strand ... [and] the Lindstrom lens illustrates a supporting strand with a somewhat irregular, elliptical shape." The addition of the "continuous, substantially circular arc" limitation to claim 16 and the statements made by Pannu to the examiner during prosecution of the '855 patent limited the claim to exclude an interpretation that did not include a continuous, substantially circular arc. *See Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576, 34 USPQ2d 1673, 1676 (1995). The shape of the haptics was broadened during reissue and was the same subject matter that was surrendered during prosecution.

Pannu argues, however, that because the reissued claims were materially narrowed in other respects, the '525 reissue

avoids the recapture rule. *See Hester*, 142 F.3d at 1482–83, 46 USPQ2d at 1649–50; *Clement*, 131 F.3d at 1470, 45 USPQ2d at 1165; *Mentor*, 998 F.2d at 996, 27 USPQ2d at 1525. Instead of being "substantially greater" than the width of the haptics, the snag resistant means must now be "at least three times greater" than the width of the haptics. In addition, the snag resistant means must now be "substantially coplanar" with the haptics. Pannu argues that both modifications relate to the configuration of the haptics, and therefore, what is gained by the elimination of one limitation is given up by the addition of the other limitations.

[12–14] The "continuous, substantially circular arc" limitation related to the shape of the haptics. The narrowing aspect of the claim on reissue, however, was not related to the shape of the haptics, but rather the positioning and dimensions of the snag resistant means. Therefore, the reissued claims were not narrowed in any material respect compared with their broadening. Furthermore, "if the patentee is seeking to recover subject matter that had been surrendered during the initial prosecution this flexibility of analysis is eliminated, for the prosecution history establishes the substantiality of the change and estops its recapture." *Anderson v. Int'l Eng'g & Mfg., Inc.*, 160 F.3d 1345, 1349, 48 USPQ2d 1631, 1634 (Fed.Cir. 1998); *see also Mentor*, 998 F.2d at 996, 27 USPQ2d at 1525 ("[I]n this case, the reissue claims are broader than the original patent claims in a manner directly pertinent to the subject matter surrendered during prosecution. Mentor thus attempted to reclaim what it earlier gave up."). In prosecuting the '855 patent, Pannu specifically limited the shape of the haptics to a "continuous, substantially circular arc." On reissue, he is estopped from attempting to recapture the precise limitation he added to overcome prior art rejections.

Conclusion

Accordingly, we affirm the judgment of the United States District Court for the Southern District of Florida.

AFFIRMED.

William E. WOODMAN, Petitioner,

v.

OFFICE OF PERSONNEL MANAGEMENT, Respondent.

No. 00–3414.

United States Court of Appeals, Federal Circuit.

July 27, 2001.

Rehearing and Rehearing En Banc Denied Oct. 2, 2001.

Former National Guard Technician (NGT) petitioned for review of final decision of the Merit Systems Protection Board (MSPB) that found him ineligible for reemployment rights under the Uniformed Services Employment and Reemployment Rights Act (USERRA). The District Court, Schall, J., held that: (1)

APPENDIX 9

Hester v. Stein

their rights on account of their incapacity. The decision in this case should come as no surprise to the Board, given its decision in *French*, or to OPM, which recognized the force of *French* when promulgating the FERS regulations for agency-filed disability retirement applications. Responding to a comment about the circumstances in which an individual's refusal to comply with a request to be examined may in itself be a symptom of a disease, OPM stated that "a recent court case, *French v. OPM*, has resulted in both OPM and the Merit Systems Protection Board taking a more active role in ensuring that such individuals have adequate legal representation before a final decision can be made in their cases." Federal Employees' Retirement System—Disability Retirement, 55 Fed.Reg. 6596, 6597 (1990) (final rule).

VIII

For the reasons set forth above, we hold that the Board correctly ruled that Mr. Harris may not reopen his appeal to challenge his removal by the DVA. However, the Board's decision is vacated and the case is remanded to determine whether the DVA breached its obligations under the Agreement and section 844.202 by failing to initiate and process a disability retirement application for Mr. Harris.

VACATED and REMANDED.

WEST KEY NUMBER SYSTEM

HESTER INDUSTRIES, INC., Plaintiff-Appellant,

v.

STEIN, INC., Defendant-Cross Appellant.

Nos. 97-1352, 97-1353.

United States Court of Appeals, Federal Circuit.

May 7, 1998.

Patentee brought action for infringement of reissue patents covering steam cookers. The United States District Court for the Eastern District of Virginia, Ellis, J., 963 F.Supp. 1403, granted summary judgment for alleged infringer, on grounds of invalidity. Patentee appealed, and alleged infringer cross-appealed, challenging district court's claim construction. The Court of Appeals, Plager, Circuit Judge, held that: (1) reissue claims violated recapture rule, due to arguments made during patent prosecution, and thus failed to satisfy reissue statute's "error" requirement; (2) requirement that reissue patent be "for the invention disclosed in the original patent" did not require objective intent, manifested in original patent, to claim invention as claimed in reissue patent; and (3) challenge to claim construction was moot.

Affirmed.

1. Patents ⇐314(5)

Whether requirements of statute governing reissue of patents have been met is question of law, although legal conclusion can involve underlying factual questions. 35 U.S.C.A. § 251.

2. Patents ⇐135

"Error" requirement of statute governing reissue of patents limits availability of reissue patent to certain correctable errors such as where patentee has claimed invention too broadly or too narrowly. 35 U.S.C.A. § 251.

3. Patents ⇐135

"Original patent" requirement of statute governing reissue of patents is independent requirement which restricts reissue patent to invention disclosed in original patent. 35 U.S.C.A. § 251.

4. Patents ⇐134

Statute governing reissue of patents is based on fundamental principles of equity and fairness, and should be construed liberally. 35 U.S.C.A. § 251.

5. Patents ⇐135

Not every event or circumstance that might be labeled "error" is correctable by reissue patent. 35 U.S.C.A. § 251.

6. Patents ⇐139

Recapture rule is regaining through reissue that he surrendered in ance of original claim reissue statute's "error such surrender is not "error" contemplated U.S.C.A. § 251.

7. Patents ⇐141(4)

Claims of reissue ers which omitted original patent claim cooked solely with have two sources of rule, and thus failed ute's "error" requirement dered claim scope that limitations, by repeatedly limitations distinguished prior art, surrendered "crept back" into reissue claims were not material other respect. 35 U.S.C.

8. Patents ⇐141(3.1)

Application of recapture vents reissue claims that original patent claims in pertinent to subject matter prosecution, begins with whether and in what respect are broader than original sue claim that does not present in original patent in that respect. 35 U.S.C.A.

9. Patents ⇐141(2)

To determine whether surrendered particular subject purpose of determining whether patent, Court of Appeals looks history for arguments and made in effort to overcome tion. 35 U.S.C.A. § 251.

reissue patent; indeed, reissue procedure does not give patentee the right to prosecute de novo his original application. 35 U.S.C.A. § 251.

6. Patents ⇐139

Recapture rule prevents patentee from regaining through reissue subject matter that he surrendered in effort to obtain allowance of original claims; rule is rooted in reissue statute's "error" requirement in that such surrender is not the type of correctable "error" contemplated by statute. 35 U.S.C.A. § 251.

7. Patents ⇐141(4)

Claims of reissue patent for steam cookers which omitted limitations, present in original patent claim, requiring that food be cooked solely with steam and that cooker have two sources of steam violated recapture rule, and thus failed to satisfy reissue statute's "error" requirement; inventor surrendered claim scope that did not include such limitations, by repeatedly arguing that those limitations distinguished original claims from prior art, surrendered subject matter had "crept back" into reissue claims, and reissue claims were not materially narrowed in any other respect. 35 U.S.C.A. § 251.

8. Patents ⇐141(3.1)

Application of recapture rule, which prevents reissue claims that are broader than original patent claims in manner directly pertinent to subject matter surrendered during prosecution, begins with determination of whether and in what respect reissue claims are broader than original patent claims; reissue claim that does not include limitation present in original patent claims is broader in that respect. 35 U.S.C.A. § 251.

9. Patents ⇐141(2)

To determine whether patent applicant surrendered particular subject matter, for purpose of determining validity of reissue patent, Court of Appeals looks to prosecution history for arguments and changes to claims made in effort to overcome prior art rejection. 35 U.S.C.A. § 251.

10. Patents ⇐141(3.1)

Patent claim amendments are relevant to determination of whether reissue patent violates recapture rule, because amendment to overcome prior art rejection evidences admission that original claim was not patentable. 35 U.S.C.A. § 251.

11. Patents ⇐141(6)

Arguments made by patent applicant to overcome prior art can alone evidence admission of unpatentability sufficient to give rise to finding of surrender, for purpose of claim that reissue patent is invalid under recapture rule, even when arguments are made in absence of any claim amendment. 35 U.S.C.A. § 251.

12. Patents ⇐141(3.1)

Recapture rule, which precludes reissue claims that are broader than original patent claims in manner directly pertinent to subject matter surrendered during prosecution, may be avoided where reissue claims were materially narrowed in other respects. 35 U.S.C.A. § 251.

13. Patents ⇐226.7

Use of word "means" in patent claim clause triggers presumption that statute governing means-plus-function claims applies, although presumption can be overcome if clause recites sufficient structure. 35 U.S.C.A. § 112.

14. Patents ⇐135

Statutory requirement that reissue patent be "for the invention disclosed in the original patent" did not require objective intent, manifested in original patent, to claim invention as claimed in reissue patent. 35 U.S.C.A. § 251.

15. Patents ⇐324.2

Alleged patent infringer's challenge to district court's construction of patent claims was moot, where asserted claims were invalid for failure to comply with reissue statute. 35 U.S.C.A. § 251.

Robert W. Adams, Nixon & Vanderhye, P.C., Arlington, VA, argued for plaintiff-appellant. With him on the brief were Robert

A. Vanderhye, James T. Hosmer, Robert W. Faris, and William J. Griffin.

Charles H. De La Garza, Arnold, White & Durkee, Minneapolis, MN, argued for defendant-cross appellant. With him on the brief were L. Gene Spears, Attorney of Record, and James C. Pistorino, Houston, TX.

Before PLAGER and SCHALL, Circuit Judges.[1]

PLAGER, Circuit Judge.

Hester Industries, Inc. ("Hester") appeals from a summary judgment of invalidity entered by the United States District Court for the Eastern District of Virginia. The district court ruled that the reissue patent claims asserted by Hester against Stein, Inc. ("Stein") are invalid for failing to meet the statutory "error" and "original patent" requirements for reissue patents set forth in 35 U.S.C. § 251 ¶ 1 (1994). *Hester Indus., Inc. v. Stein, Inc.*, 963 F.Supp. 1403 (E.D.Va. 1997). Stein cross-appeals a pretrial oral ruling in which the district court adopted Hester's proposed construction of the claim term "high humidity steam."

Because the asserted reissue claims impermissibly recapture subject matter surrendered by Hester through deliberate arguments repeatedly made to the Patent Office to overcome prior art, we hold that Hester is barred from asserting "error" within the meaning of 35 U.S.C. § 251 ¶ 1. We accordingly affirm the summary judgment of invalidity. Because the asserted claims are invalid, we need not and do not reach the claim construction issue.

BACKGROUND

At issue in this case are two reissue patents, U.S. Patent No. Re. 33,510 (the "'510 reissue patent") and U.S. Patent No. Re. 35,259 (the "'259 reissue patent"). The two patents are reissues of the same original patent, U.S. Patent No. 4,582,047 (the "'047 patent" or "original patent"), which they replaced pursuant to 35 U.S.C. § 251.[2] The patents are directed to a high humidity steam cooker having a continuously running conveyor for cooking food items such as poultry and other meat products. Hester, a processor of pre-cooked poultry and other meat products, owns the patents, and Charles E. Williams ("Williams"), a Hester employee, is the sole named inventor. After the '259 reissue patent (the second reissue) issued in 1996, Hester sued Stein, a manufacturer of industrial appliances, for allegedly infringing several reissue claims in the two reissue patents.

The two reissue patents and the original patent have the same written description; the patents differ only with respect to their claims. That written description describes an industrial-size steam cooker for cooking large quantities of food products. The cooker is described as having a cooker chamber in which a steam atmosphere is maintained. The food products are carried through the cooker chamber on a conveyor belt that runs through a spiral path. The written description teaches that efficient cooking is achieved without the loss of humidity, flavor, or appearance by maintaining a water-drop-free steam atmosphere within the chamber at near 100°C and 100% humidity, at above atmospheric pressure.

A.

Two separate sources of steam, one internal and one external, are described for maintaining the steam atmosphere. The internal source of steam described is a pool of water on the floor of the cooker chamber, heated by a heating element in the pool. The external source described is a steam generator, located outside the cooker chamber and connected by pipes to various locations within the cooker chamber to inject steam at those locations. The written description states that the external steam source typically provides 25% of

1. A member of the panel that heard argument in this case was unable to continue with consideration of the case because of recusal. Pursuant to Rule 47.11 of this court, the matter was decided by the remaining members of the panel.

2. The district court noted that the issuance of two reissue patents for the same original patent was a "curiosity" that appeared to be unprecedented. *Hester*, 963 F.Supp. at 1405 n. 2. However, the propriety of two reissues for the same patent was not addressed below and has not been raised on appeal. Accordingly, we express no opinion on the matter.

the steam, with the remainder provided by the internal source. '047 patent, col. 3, ll. 42–45, 57–59. The heating element in the internal steam source is controlled to maintain the desired amount of steam and pressure within the cooker chamber. *Id.* col. 3, ll. 59–63.

The section of the written description entitled DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT describes the cooking atmosphere thus:

> The cooking is solely with water droplet free steam near 100°C. and 100% humidity at a pressure above atmospheric. The high humidity atmosphere prevents losses of humidity of the product as it passes through the cooker and helps retain juices, essences and flavor of the product. Also it improves the heating steam interface heat exchange at the product surface for more efficient cooking.
>
> The higher pressure not only produces a pressure-cooker like cooking efficiency to the cooking process, but is critical in connection with the flavor and conveyor type product flow as well.

Id. col. 3, ll. 22–33.

The original patent contains one independent claim, claim 1, directed to a food cooking system. The claim specifies that the cooking system cooks solely with steam and that the system includes two sources of steam to provide the steam atmosphere. Characteristics of the steam atmosphere are set forth, and the cooking system is said to include a means passing a conveyor belt through the cooker housing. Claim 1, with relevant text emphasized, reads:

> A food cooking system *cooking solely with steam* foods such as fish, fowl, meats or produce carried through a cooker on a continuously running conveyor belt, comprising in combination, a cooker housing, *means passing said conveyor belt through said housing* to expose food products within the cooker housing only to *said steam as the sole cooking medium*, and *two sources of steam providing said steam* to cook the food products, nozzles for releasing steam located inside said housing, one comprising a steam generator supplying supplemental steam into said housing at said nozzles located thereinside *to maintain the atmosphere together with the other steam source at near 100% humidity 100°C. and a pressure above atmospheric*, and the other source of steam comprising a pool of water within said housing with heating means for boiling the water to create steam.

Id. col. 5, l. 59 to col. 6, l. 8. For purposes here, this is substantially the same form in which the claim was first filed (as application claim 1) in the application for the original patent. Accordingly, we do not distinguish between the issued claim and the application claim, but instead simply refer to claim 1.

In addition to the independent claim, the original patent contains several claims which are dependent upon claim 1. Relevant here is dependent claim 12, which specifies in pertinent part: "A system as defined in claim 1 *wherein the conveyor belt is passed* inside said housing *in a spiral path* coiling downwardly . . ." *Id.* col. 6, ll. 59–61 (emphasis added). This claim stemmed from original application claim 16, which specified that the conveyor belt is "passed . . . in a spiral path."

The application for the '047 patent (the original patent) was filed in 1979. The patent did not issue until 1986, nearly seven years later. Over the almost seven years in which the application was prosecuted before the United States Patent and Trademark Office ("Patent Office"), inventor Williams, through his attorney, repeatedly emphasized the "solely with steam" and "two sources of steam" features of the claimed invention in attempting to establish patentability over the prior art. For example, after the Examiner first rejected claim 1 as well as all the other claims as obvious, Office Action of Feb. 6, 1980, at 2, Williams distinguished a cited prior art cooker that cooked with a combination of infra-red dry heat and steam on the ground that the claimed invention cooked solely with steam, stating: "This principle is completely different from applicant's invention where the claims define cooking *solely* with steam." Applicant Response of Apr. 28, 1980 (emphasis in original). Williams also distinguished claim 1 on the basis of the "two sources of steam" limitation, the specified characteristics of the steam atmosphere, and

the recited continuously running conveyor belt. *Id.*

Application claim 16, which specified a spiral conveyance path, was rejected as obvious in view of an additional prior art cooker that included a spiral conveyor. Office Action of Feb. 6, 1980, at 4. In response, Williams amended claim 16 to specify further details of the spiral conveyance path and then argued that the claimed spiral conveyance path was distinguished from that shown in the prior art. Applicant Response of Apr. 28, 1980.

However, the Examiner continued to reject all claims as obvious. Office Action of July 9, 1980. At that point, Williams placed even greater reliance on the "solely with steam" and "two sources of steam" limitations in an attempt to overcome the obviousness rejection. For example, in his first appeal of the obviousness rejection to the Board of Patent Appeals and Interferences ("Board"), Williams stated, "The claimed system cooks *solely* with steam ... by means of two separate and critical steam sources...." Applicant Brief on Appeal, at 2 (Aug. 20, 1980) (emphasis in original). Later in the same brief, Williams specifically distinguished the cited prior art on the basis of these limitations:

> The primary reference Vischer cooks with IR radiation not steam. Clearly the claimed feature of cooking *solely* with steam is directly contrary to the teaching of the Vischer patent, which could therefore never make obvious any process or equipment cooking *solely* with steam as claimed.
>
> ....
>
> The Examiner errs in any implication that Jourdan shows two sources of steam.

Id. at 9–10 (emphasis in original).

Prior to the Board hearing Williams' appeal, the Examiner reopened prosecution on the merits in view of newly discovered prior art, thereby removing the appeal from the Board.[3] Office Action of Mar. 17, 1981. The Examiner then rejected all of the claims as obvious over the new prior art. *Id.* In response, Williams distinguished claim 1 over that prior art on the same bases, *i.e.*, the "solely with steam" and "two sources of steam" limitations. Applicant Response to Office Action (Apr. 17, 1981). However, the Examiner was not persuaded, even after these same arguments were repeated in subsequent papers submitted to the Patent Office.

Accordingly, Williams initiated a second appeal to the Board. He again emphasized the "solely with steam" and "two sources of steam" limitations. Applicant Brief on Appeal, at 13 (Dec. 22, 1981). He explained that the two sources of steam interact to provide a "synergy" that is "novel and nowhere suggested in any of the cited [prior] art." *Id.* Williams drove home his reliance on the "solely with steam" limitation most forcefully in his reply brief to the Board: "Clearly the Examiner reversibly errs as a matter of fact and in his efforts to make a case out against the *very material claimed feature that steam is the sole cooking medium (claim 1).* Thus reversal is respectfully solicited." Applicant Reply Brief on Appeal, at 6 (Sep. 30, 1982) (emphasis in original).

The Board was persuaded and accordingly reversed the obviousness rejection in its opinion dated June 21, 1985, stating:

> [W]e find no suggestion in the combined teachings of the references which would have led the ordinarily skilled worker in the art to an apparatus utilizing steam as the sole cooking medium, utilizing two separate sources of steam, one of which includes a pool of water in the cooking chamber with means for boiling the water, and wherein the atmosphere within the cooking chamber is maintained above atmospheric by the two sources of steam.

Thereafter the claims were allowed and the application issued as the '047 patent on April 15, 1986.

On the two-year anniversary of the '047 patent's issuance, Williams applied for a reissue pursuant to 35 U.S.C. § 251, alleging that the patent claims had been drawn too narrowly due to attorney error. In the required oath accompanying the reissue application, Williams explained that he became

3. Accordingly, the Board never heard Willams' first appeal.

aware of this alleged error after learning that Stein was in the process of developing a competing cooker in early 1988. According to his oath, Williams and his employer Hester concluded that the '047 patent should cover the Stein cooker, notwithstanding the fact that the cooker used a non-steam heat source and only one source of steam in the cooking process. Williams further explained that Hester's present counsel advised Hester that the '047 patent claims, as written, might not cover Stein's cooker. Thus, Williams, by oath, declared that the patent was insufficient because it claimed less than he had a right to claim.

Specifically, Williams identified two relevant deficiencies of the '047 patent, as follows (indentation and numbering added): [4]

> [1] that each of claims 1–14 therein requires cooking "solely with steam" and exposing food products within the cooker housing "only to said steam as the sole cooking medium" . . . . [and]
>
> [2] that each of claims 1–14 therein requires "'two sources of steam providing said steam to cook the food products, nozzles for releasing steam located inside said housing"[.]

These deficiencies, according to Williams, "arose after [he] executed and filed the original application from which the '047 patent issued" and were caused by "the failure of [his prior] patent attorney . . . to appreciate the full scope of [his] invention."

This application ripened into the '510 reissue patent nearly three years later on January 1, 1991. However, prior to its issuance, Williams filed a second reissue application, for reasons not relevant here, on June 21, 1990, alleging the same errors used to support the first reissue. Six years later, this second reissue application issued as the '259 reissue patent. Hester then filed this action, accusing Stein of infringing two claims in the first reissue patent and six claims in the second. Specifically, Hester accused Stein of infringing reissue claims 26 and 59 of the '510 reissue patent and reissue claims 28, 30, 31, 32, 75, and 76 of the '259 reissue patent.

The requirement in original claim 1 that cooking is "solely with steam" is absent from each of the asserted reissue claims. Also absent is the "two sources of steam" limitation. Rather, the asserted reissue claims merely recite a source of steam or at least one source of steam. None of the asserted reissue claims explicitly recite the steam atmosphere characteristics specified in original claim 1, *i.e.*, the characteristics of near 100C and 100% humidity at above atmospheric pressure. Instead, all but one of the asserted reissue claims recite "high humidity steam." [5]

Claim 26 of the '510 reissue patent is representative of the two asserted reissue claims in that patent. It provides in pertinent part:

> A food cooking system for cooking food products carried on a moving conveyor belt, comprising:
>
> a cooker housing[,]
>
> *means disposed within said housing for defining a conveyance path,*
>
> a conveyor belt disposed along said conveyance path for supporting and conveying said food products along said path,
>
> means coupled to said belt for causing said belt and said food products supported thereby to substantially continually translate along said conveyance path . . ., and
>
> *a source of steam providing steam to contact and cook the food products, said steam source comprising at least one of the following:*
>
> an external steam generator supplying steam into said housing, and
>
> a pool of water within said housing with heating means communicating with said pool of water for creating steam . . . [,]
>
> [4] "a pool of water within the housing with heating means for boiling the water to create steam."
>
> (Indentation and numbering added.)

4. The reissue oath specifies two further insufficiencies, namely, that the '047 patent requires:

> [3] "a steam generator supplying supplemental steam into said housing at said nozzles located thereinside to maintain the atmosphere together with the other steam source at near 100% humidity 100°C, and a pressure above atmospheric" and

5. Claim 30 of the '259 reissue patent does not contain the "high humidity steam" language.

wherein said steam source provides high humidity steam and said food products are directly exposed to said high humidity steam.

'510 patent, col. 8, ll. 8–31, 36–38 (emphasis added, and text of claim 24, upon which claim 26 depends, incorporated).

The asserted reissue claims of the '259 reissue patent are, for purposes here, substantially similar. One difference is that several of these claims explicitly recite a "spiral conveyance path." Claim 28, which is representative, provides in pertinent part:

A spiral steam cooker for at least partially cooking exposed food products, said cooker comprising:

a housing defining an internal volume therein;

a conveyor belt at least partially *disposed along a spiral conveyance path* within said internal volume . . .; and

a steam source operatively coupled to said housing, said steam source *providing a high humidity steam atmosphere* within said internal volume, said high humidity steam atmosphere directly contacting and at least partially cooking the exposed food products . . . .

'259 patent, col. 9, l. 61 to col. 10, l. 12 (emphasis added).

Before the district court, Stein moved for summary judgment that the asserted reissue claims are invalid for failing to meet the requirements of the reissue statute, 35 U.S.C. § 251. That section (with emphasis added) reads:

Whenever any patent is, through *error* without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or *by reason of the patentee claiming more or less than he had a right to claim in the patent*, the Commissioner shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent *for the invention disclosed in the original patent*, and in accordance with a new and amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue.

In particular, Stein argued that the "error" requirement of § 251 ¶ 1, as well as the requirement therein that the reissue claims be "for the invention disclosed in the original patent" (the "original patent" requirement), were not met. With regard to the "error" requirement, Stein argued that Williams had not erred in including the "solely with steam" and "two sources of steam" limitations in the original claims, and further argued that the removal of those limitations violated the "recapture" rule. Stein further argued that the asserted reissue claims violated the "original patent" requirement because, Stein asserted, the original patent does not evidence an "objective" intent to claim the invention in the manner of the asserted reissue claims.

The district court granted Stein's motion. The court first concluded that there was no "error" as contemplated by § 251 ¶ 1. Specifically, the court concluded that the alleged failure of counsel to appreciate the scope of the invention was belied by the clear language in the original patent claims, the prosecution history of the patent, and the absence of any explanation as to the nature or cause of the attorney's failure to appreciate the full scope of the invention. *Hester*, 963 F.Supp. at 1408. The court did not reach Stein's assertion that the asserted reissue claims violate the recapture rule, though the court relied heavily on the original patent's prosecution history in determining that the "error" requirement was not met. *See id.* at 1409–11.

The district court ruled that the asserted reissue claims are alternatively invalid for failing to meet the "original patent" requirement. *Id.* at 1412. The district court concluded that the "original patent" clause of § 251 ¶ 1 includes a separate requirement that the original patent manifest an "objective" intent to claim the invention as later claimed on reissue. *Id.* at 1412–13. The court concluded that the original patent does not manifest such an objective intent, and thus the claims are also invalid under the "original patent" clause of § 251 ¶ 1. *Id.* at 1412–15.

In its appeal of the invalidity judgment, Hester argues that the district court erred in concluding that the "error" and "original patent" requirements of § 251 ¶ 1 were not met.

Stein, in seeking to uphold the judgment, makes the same arguments presented to the district court in its motion for summary judgment. Hester, on the other hand, argues that the "error" requirement was met by way of prior patent counsel's failure to appreciate the full scope of the invention. Hester further asserts that the recapture rule is inapplicable because the reissue claims were never presented during prosecution of the original patent and later abandoned by amendment or cancellation. With regard to the "original patent" clause of § 251 ¶ 1, Hester submits that there is no separate requirement of a manifestation of an objective intent to claim.

Also at issue on appeal is the district court's resolution of a "Motion For Claim Interpretation" brought by Stein. In that motion, Stein argued that the claim term "high humidity steam" should be construed in accordance with the only specific description of the steam atmosphere provided in the patents, *i.e.*, as water-droplet-free steam near 100 °C and 100% humidity at above atmospheric pressure. Hester, relying on the opinion of its expert, proposed a broader construction, arguing that the description contained in the patents is merely one example of "high humidity steam." The district court, in a ruling delivered from the bench prior to holding the asserted reissue claims invalid, adopted Hester's proposed construction of the claim term. The ruling was never reduced to a formal order or judgment. The parties, by way of cross-appeal by Stein, present the same issue on appeal.

DISCUSSION

I

[1] In reviewing the summary judgment of invalidity, we keep in mind that summary judgment is appropriate only when the record shows that "there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c). Whether the statutory requirements of 35 U.S.C. § 251 have been met is a question of law. *See In re Clement*, 131 F.3d 1464, 1468, 45 USPQ2d 1161, 1163 (Fed.Cir.1997). This legal conclusion can involve underlying factual questions. *See id.*

II

[2] As previously explained, the "error" and "original patent" requirements at issue here are found in the first paragraph of § 251. The "error" requirement limits the availability of a reissue patent to certain correctable errors. *See In re Amos*, 953 F.2d 613, 616, 21 USPQ2d 1271, 1273 (Fed. Cir.1991). As seen in the above-emphasized text of § 251, one such correctable error is the patentee claiming his invention too broadly or too narrowly.[6] *See id.*

[3] The "original patent" requirement is a second and independent requirement, *see Amos*, 953 F.2d at 615, 21 USPQ2d at 1272, which restricts a reissue patent to "the invention disclosed in the original patent." 35 U.S.C. § 251 ¶ 1. We address each of these requirements in turn.

A

1

[4, 5] In considering the "error" requirement, we keep in mind that the reissue statute is "based on fundamental principles of equity and fairness, and should be construed liberally." *In re Weiler*, 790 F.2d 1576, 1579, 229 USPQ 673, 675 (Fed.Cir.1986). We also keep in mind that "not every event or circumstance that might be labeled 'error' is correctable by reissue." *Id.* Indeed, the reissue procedure does not give the patentee the right "to prosecute *de novo* his original application." *Id.* at 1582, 790 F.2d 1576, 229 USPQ at 677; *see also Mentor Corp. v. Coloplast, Inc.*, 998 F.2d 992, 995, 27 USPQ2d 1521, 1524 (Fed.Cir.1993).

One of the most commonly asserted "errors" in support of a broadening reissue is the failure of the patentee's attorney to appreciate the full scope of the invention during the prosecution of the original patent application. *See Amos*, 953 F.2d at 616, 21 USPQ2d

6. The last paragraph of § 251 requires that a request to enlarge the scope of claims be "applied for within two years from the grant of the original patent." 35 U.S.C. § 251 ¶ 4 (1994).

at 1273; *In re Wilder*, 736 F.2d 1516, 1519, 222 USPQ 369, 371 (Fed.Cir.1984). This form of error has generally been accepted as sufficient to satisfy the "error" requirement of § 251. *See Clement*, 131 F.3d at 1468, 45 USPQ2d at 1163; *Wilder*, 736 F.2d at 1519, 222 USPQ at 371. Williams asserted this form of error as the basis for his reissue applications, and the Patent Office accepted his assertion as adequate.

However, the district court concluded that there was no such error by Williams' attorney. *Hester*, 963 F.Supp. at 1411. In reaching this conclusion, the court was particularly persuaded by the prosecution history of the original patent. The court concluded that the attorney's repeated attempts to distinguish Williams' invention on the basis of the "solely with steam" and "two sources of steam" limitations belied Williams' assertion that his attorney failed to appreciate the full scope of his invention. *Id.* at 1409–11. The court also determined that there was no other form of § 251 "error" and thus held the asserted reissue claims invalid. *Id.* at 1411–12.

2

[6] We share the district court's discomfort with Williams' attempt to remove, through reissue, the "solely with steam" and "two sources of steam" limitations after having relied so heavily on those limitations to obtain allowance of the original patent claims over the prior art. This concern is addressed most squarely by the "recapture rule," recently discussed at length in *Clement*, 131 F.3d 1464, 45 USPQ2d 1161. The recapture rule "prevents a patentee from regaining through reissue ... subject matter that he surrendered in an effort to obtain allowance of the original claims." *Clement*, 131 F.3d at 1468, 45 USPQ2d at 1164. The rule is rooted in the "error" requirement in that such a surrender is not the type of correctable "error" contemplated by the reissue statute. *See Mentor*, 998 F.2d at 995–96, 27 USPQ2d at 1525.

[7] In its motion for summary judgment, Stein presented the recapture rule as one basis for finding the asserted reissue claims invalid, and Stein repeats this argument on appeal as one basis for affirming the summary judgment of invalidity. While the district court did not explicitly rule on this ground, its opinion indicates the view that Hester, through the reissue patents, recaptured surrendered subject matter. *Hester*, 963 F.Supp. at 1412 (stating that through the reissues, Hester obtained claims covering "ovens with characteristics repeatedly distinguished and disclaimed in the PTO" and that that was contrary to the "error" requirement of § 251). As will be next explained, we conclude that the asserted reissue claims violate the recapture rule and that the summary judgment ruling is appropriately affirmed on this ground.

[8] "Under [the recapture] rule, claims that are 'broader than the original patent claims in a manner directly pertinent to the subject matter surrendered during prosecution' are impermissible." *Clement*, 131 F.3d at 1468, 45 USPQ2d at 1164 (quoting *Mentor*, 998 F.2d at 996, 27 USPQ2d at 1525). Application of the recapture rule begins with a determination of whether and in what respect the reissue claims are broader than the original patent claims. *See id.* A reissue claim that does not include a limitation present in the original patent claims is broader in that respect. *See id.* Here, it is undisputed that the asserted reissue claims are broader than the original patent claims in that the reissue claims do not include the "solely with steam" and "two sources of steam" limitations found in each of the original patent claims.

[9] Having determined that the reissue claims are broader in these respects, under the recapture rule we next examine whether these broader aspects relate to surrendered subject matter. *See id.* at 1468–69, 131 F.3d 1464, 45 USPQ2d at 1164. "To determine whether an applicant surrendered particular subject matter, we look to the prosecution history for *arguments* and changes to the claims made in an effort to overcome a prior art rejection." *Id.* at 1469, 131 F.3d 1464, 45 USPQ2d at 1164 (emphasis added). This statement in *Clement* indicates that a surrender can occur by way of arguments *or* claim changes made during the prosecution of the

original patent application. To date, the cases in which this court has found an impermissible recapture have involved claim amendments or cancellations. *See, e.g., id.* at 1469–70, 131 F.3d 1464, 45 USPQ2d at 1164–65; *Mentor*, 998 F.2d at 995–96, 27 USPQ2d at 1524–25. However, in addition to the suggestion in *Clement* that argument alone can effect a surrender, this court expressly left open that possibility in *Ball Corp. v. United States:* "If reissue is sought where claims have not been previously canceled, analysis becomes more difficult. In that case relative claim scope is not available to illuminate the alleged error. We are not faced with that situation in this proceeding." 729 F.2d 1429, 1436 n. 19, 221 USPQ 289, 295 n. 19 (Fed.Cir.1984). Prior to this case, this court has not squarely addressed the question.

[10] This court's prior opinions indicate that, as a general proposition, in determining whether there is a surrender, the prosecution history of the original patent should be examined for evidence of an admission by the patent applicant regarding patentability. *See Clement*, 131 F.3d at 1468, 45 USPQ2d at 1164 (noting that, with regard to claim amendments, the recapture rule does not apply in the absence of evidence that the amendment was an admission that the scope of the claim was not patentable); *Mentor*, 998 F.2d at 995, 27 USPQ2d at 1524 (same); *Seattle Box Co. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 826, 221 USPQ 568, 574 (Fed.Cir.1984) (declining to apply the recapture rule when there was no evidence that the "amendment ... was in any sense an admission that the scope of [the] claim was not patentable"). In this regard, claim amendments are relevant because an amendment to overcome a prior art rejection evidences an admission that the claim was not patentable. *See Mentor*, 998 F.2d at 995–96, 27 USPQ2d at 1524–25 (finding surrender by way of claim amendments); *Ball*, 729 F.2d at 1436, 221 USPQ at 294 (noting that a court may draw inferences from changes in claim scope).

[11] Arguments made to overcome prior art can equally evidence an admission sufficient to give rise to a finding of surrender. Indeed, in *Mentor* and *Clement* the findings of a surrender were based in part on the arguments made in conjunction with the claim amendments. *Mentor*, 998 F.2d at 995–96, 27 USPQ2d at 1524–25; *Clement*, 131 F.3d at 1470–71, 45 USPQ2d at 1165–66. Logically, this is true even when the arguments are made in the absence of any claim amendment. Amendment of a claim is not the only permissible predicate for establishing a surrender.

The view that arguments alone can give rise to a surrender is consistent with the policy behind the reissue statute and the accompanying recapture rule. As already noted, the reissue statute is "based on fundamental principles of equity and fairness." *Weiler*, 790 F.2d at 1579, 229 USPQ at 675. There is no unfairness in binding the patentee to deliberate assertions made in order to obtain allowance of the original patent claims over the prior art. Indeed, fairness to the public must also be considered. In this regard, as stated in *Mentor*, "the reissue statute cannot be construed in such a way that competitors, properly relying on prosecution history, become patent infringers when they do so." 998 F.2d at 996, 27 USPQ2d at 1525. The recapture rule operates to prevent this from happening. *See id.* Furthermore, as recognized in *Ball*, the recapture rule is based on principles of equity and therefore embodies the notion of estoppel. 729 F.2d at 1439, 221 USPQ at 296.

Indeed, the recapture rule is quite similar to prosecution history estoppel, which prevents the application of the doctrine of equivalents in a manner contrary to the patent's prosecution history. *See Warner–Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, ——, 117 S.Ct. 1040, 1051, 137 L.Ed.2d 146 (1997). Like the recapture rule, prosecution history estoppel prevents a patentee from regaining subject matter surrendered during prosecution in support of patentability. *See id.*

Hester argues that an analogy cannot be made with prosecution history estoppel because the reissue procedure and prosecution history estoppel are the antithesis of one another—reissue allows an expansion of patent rights whereas prosecution history estop-

pel is limiting. However, Hester's argument is unpersuasive. The analogy is not to the broadening aspect of reissues. Rather, the analogy is with the recapture rule, which restricts the permissible range of expansion through reissue just as prosecution history estoppel restricts the permissible range of equivalents under the doctrine of equivalents.

This court earlier concluded that prosecution history estoppel can arise by way of unmistakable assertions made to the Patent Office in support of patentability, just as it can by way of amendments to avoid prior art. *See, e.g., Texas Instruments, Inc. v. International Trade Comm'n*, 988 F.2d 1165, 1174, 26 USPQ2d 1018, 1025 (Fed.Cir.1993). The same reasoning that led us to conclude that arguments alone can give rise to prosecution history estoppel lends support to the proposition that arguments alone can give rise to a surrender for purposes of the recapture rule.

Thus we conclude that, in a proper case, a surrender can occur through arguments alone. We next evaluate whether such a surrender occurred here with respect to the "solely with steam" and "two sources of steam" limitations, the pertinent aspects in which the asserted reissue claims are broader than the original patent claims. The obvious conclusion is that there has been a surrender.

As detailed above, Williams repeatedly argued that the "solely with steam" and "two sources of steam" limitations distinguished the original claims from the prior art. These were Williams' primary bases for distinguishing the broadest claim, independent claim 1, from the prior art. At no less than 27 places in six papers submitted to the Patent Office, Williams asserted that the "solely with steam" limitation distinguished the claimed invention from the prior art, and Williams did the same with respect to the "two sources of steam" limitation at no less than 15 places in at least five papers.

Williams argued that each of these limitations was "critical" with regard to patentability, and Williams further stated that the "solely with steam" limitation was "very material" in this regard. In essence, these repeated arguments constitute an admission by Williams that these limitations were necessary to overcome the prior art. Indeed, when the Board reversed the Examiner's rejection of the original claims, these were the primary bases indicated for patentability. Williams, through his admission effected by way of his repeated prosecution arguments, surrendered claim scope that does not include these limitations.

Having concluded that there has been a surrender, we must next determine whether the surrendered subject matter has crept back into the asserted reissue claims. *See Clement*, 131 F.3d at 1469, 45 USPQ2d at 1164. When the surrender occurs by way of claim amendment or cancellation, "[c]omparing the reissue claim with the canceled claim is one way to do this." *See id.* This analysis is not available when the surrender is made by way of argument alone. Instead, in this case, we simply analyze the asserted reissue claims to determine if they were obtained in a manner contrary to the arguments on which the surrender is based.

Clearly they were. None of the asserted reissue claims include either the "solely with steam" limitation or the "two sources of steam" limitation. Thus, this surrendered subject matter—*i.e.*, cooking other than solely with steam and with at least two sources of steam—has crept into the reissue claims. The asserted reissue claims are unmistakably broader in these respects.

[12] Finally, because the recapture rule may be avoided in some circumstances, we consider whether the reissue claims were materially narrowed in other respects. *See, e.g., Mentor*, 998 F.2d at 996, 27 USPQ2d at 1525 ("Reissue claims that are broader in certain respects and narrower in others may avoid the effect of the recapture rule."); *Clement*, 131 F.3d at 1470, 45 USPQ2d at 1165. For example, in *Ball* the recapture rule was avoided because the reissue claims were sufficiently narrowed (described by the court as "fundamental narrowness") despite the broadened aspects of the claims. 729 F.2d at 1438, 221 USPQ at 296. In the context of a surrender by way of argument, this principle, in appropriate cases, may operate to overcome the recapture rule when the reissue claims are materially narrower in

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other overlooked aspects of the invention. The purpose of this exception to the recapture rule is to allow the patentee to obtain through reissue a scope of protection to which he is rightfully entitled for such overlooked aspects.

However, this is not such a case. The asserted reissue claims are not materially narrower, despite Hester's arguments to the contrary. Hester argues that the claims are materially narrower by the addition of the "spiral conveyance path" and "high humidity steam" limitations. The term "high humidity steam" is included in each of the asserted reissue claims except reissue claim 30 of the '259 reissue patent. However, the term "high humidity steam" is actually the same as or broader than the limitation in original claim 1 that this term replaced. Original claim 1 specifies a steam atmosphere "at near 100% humidity 100°C and a pressure above atmospheric." '047 patent, col. 6, ll. 3–4. Hester concedes that the term "high humidity steam" is not narrower than this limitation in original claim 1. In fact, with respect to the claim construction issue, Hester argues that the limitation in original claim 1 is but one example of "high humidity steam." Accordingly, the use of the term "high humidity steam" does not save the reissue claims from the recapture rule.

[13] The term "spiral conveyance path" is also not materially limiting. This term appears explicitly in asserted reissue claims 28, 32, 75, and 76 of the '259 reissue patent; it does not appear explicitly in the other reissue claims asserted. Original claim 1 includes a corresponding limitation, namely, "means passing said conveyor belt through said housing . . . ." This is a so-called means-plus-function clause drafted pursuant to 35 U.S.C. § 112 ¶ 6 (1994).[7] According to § 112 ¶ 6, the clause is to be construed to "cover the corresponding structure . . . described in the specification and equivalents thereof." The only corresponding structure described in the specification (more properly, the written description of the patent) passes the conveyor belt through a spiral path. *See* '047 patent, col. 4, l. 64 to col. 5, l. 8. Thus, the explicit recitation of a "spiral conveyance path" in some of the asserted reissue claims does not materially narrow those claims. Indeed, Hester does not explain how the explicit recitation of a spiral conveyance path—which is present in prior art cookers cited by the examiner during the prosecution of the original patent—materially narrows these claims. In sum, neither alone nor together do the terms "high humidity steam" and "spiral conveyance path" materially narrow the claims.

Furthermore, the "spiral conveyance path" and "high humidity steam" limitations are not aspects of the invention that were overlooked during prosecution of the original patent. To the contrary, as just explained, these aspects were included in original claim 1. Additionally, with regard to the "spiral conveyance path" limitation, original dependent claim 12 explicitly recites "a spiral path." '047 patent, col. 6, l. 60. In prosecuting the original patent, Williams pointed out these features in an attempt to overcome the Examiner's obviousness rejection. Hester cannot now argue that Williams overlooked these aspects during the prosecution of the original patent application. In conclusion, this is not a case which involves the addition of material limitations that overcome the recapture rule.

In effect, Hester, through eight years of reissue proceedings, prosecuted Williams' original patent application anew, this time placing greater emphasis on aspects previously included in the original patent claims and removing limitations repeatedly relied upon to distinguish the prior art and described as "critical" and "very material" to the patentability of the invention. The reissue statute is to be construed liberally, but not that liberally. The realm of corrections contemplated within § 251 does not include recapturing surrendered subject matter, without the addition of materially-narrowing

7. Use of the word "means" in a claim clause triggers a presumption that § 112 ¶ 6 applies. *See York Prods., Inc. v. Central Tractor Farm & Family Ctr.*, 99 F.3d 1568, 1574, 40 USPQ2d 1619, 1623–24 (Fed.Cir.1996). The presumption can be overcome if the clause recites sufficient structure. *See id.* The clause at issue here recites no structure for performing the function of passing the conveyor belt through the housing. Accordingly, § 112 ¶ 6 unquestionably applies.

limitations, in an attempt to 'custom-fit' the reissue claims to a competitor's product.

No doubt if two patent attorneys are given the task of drafting patent claims for the same invention, the two attorneys will in all likelihood arrive at somewhat different claims of somewhat different scope. And such differences are even more likely when, as here, the second attorney drafts the new claims nearly a decade later and with the distinct advantage of having before him the exact product offered by the now accused infringer. This reality does not justify recapturing surrendered subject matter under the mantra of "failure to appreciate the scope of the invention." The circumstances of the case before us simply do not fit within the concept of "error" as contemplated by the reissue statute. *See Mentor*, 998 F.2d at 996, 27 USPQ2d at 1525 ("Error under the reissue statute does not include a deliberate decision to surrender specific subject matter in order to overcome prior art, a decision which in light of subsequent developments in the marketplace might be regretted.").

With respect to the recapture issue, there are no underlying material facts as to which there is a genuine issue in dispute. The original patent's prosecution history, on which we rely, is before us and undisputed. All that remains is the ultimate legal conclusion as to whether the asserted reissue claims fail to meet the "error" requirement because the claims impermissibly recapture surrendered subject matter. *See id.* at 994, 998 F.2d 992, 27 USPQ2d at 1524 (stating that whether the "error" requirement has been met is a legal conclusion). For the reasons explained above, we conclude as a matter of law that the asserted reissue claims fail in this regard. Summary judgment of invalidity of the asserted reissue claims under § 251 is called for. Accordingly, we affirm the district court's entry of summary judgment.

B

[14] As an alternative basis for holding the asserted reissue claims invalid, the district court concluded that the reissue claims do not meet the "original patent" clause of § 251 ¶ 1, which requires that the reissue patent be "for the invention disclosed in the original patent." *Hester*, 963 F.Supp. at 1412. In reaching this conclusion, the court interpreted the "original patent" clause as requiring an "objective" intent, manifested in the original patent, to claim the invention as claimed in the reissue patent. *Id.* The court based this interpretation on the Supreme Court's statement in *U.S. Industrial Chemicals, Inc. v. Carbide & Carbon Chemicals Corp.*, 315 U.S. 668, 676, 62 S.Ct. 839, 843–44, 86 L.Ed. 1105 (1942), that there was an objective intent requirement under the predecessor reissue statute, 35 U.S.C. § 64 (1964), which required that the reissue patent be "for the same invention." *Id.* at 1413.

Based on this construction of the "original patent" clause, the district court framed the issue as, "whether the 047 patent manifests an objective intent to cover ovens that utilize heat sources other than steam, and have less than two steam sources." *Id.* The district court concluded that the asserted reissue claims failed to meet this test and thus were invalid under the "original patent" clause. *Id.* at 1413–15. On appeal, the parties focus on whether the "original patent" clause embodies the requirement of an objective intent to claim.

This court squarely addressed the issue in *Amos*, 953 F.2d at 616, 21 USPQ2d at 1273. The *Amos* court held that § 251 does not include a separate requirement of an objective intent to claim. 953 F.2d at 618–19, 21 USPQ2d at 1275–76. Rather, the court concluded: "the essential inquiry under the 'original patent' clause of § 251 . . . is whether one skilled in the art, reading the specification, would identify the subject matter of the new claims as invented and disclosed by the patentees." *Id.* at 618, 953 F.2d 613, 21 USPQ2d at 1275. The court noted that this inquiry is analogous to the "written description" requirement of 35 U.S.C. § 112 ¶ 1 (1994). *Id.* The court further stated that, to the extent the construct of an objective intent to claim is useful, it is "only one factor that sheds light" on whether the "original patent" clause of § 251 is satisfied. *Id.* at 619 & n. 2, 21 USPQ2d at 1275–76 & n. 2 (quoting *In re Hounsfield*, 699 F.2d 1320,

1323, 216 USPQ 1045, 1(1983)).

With regard to the Supre ion in *U.S. Industrial*, 315 U 839, 86 L.Ed. 1105, the *A* that that case was decided u cessor reissue statute which claims to be for the "same concluded that *U.S. Industri* mandate a separate "obje claim" requirement. *Id.* T noted that this court reache clusion eight years earlier in F.2d at 1323, 216 USPQ a

Thus, the district court's the "original patent" clause o satisfied based on an "obje claim" requirement was in er not contend that the test set for the "original patent" clause one skilled in the art woul subject matter of the reissue vented and disclosed by the p met by the asserted reissue cl Stein relies entirely on its there is an "objective intent quirement and that that requ met. However, we need no issue further, having already the asserted reissue claims a failing to meet the "error" r § 251.

III

[15] Finally, Stein present question of whether the district

1323, 216 USPQ 1045, 1047–48 (Fed.Cir. 1983)).

With regard to the Supreme Court's opinion in *U.S. Industrial*, 315 U.S. 668, 62 S.Ct. 839, 86 L.Ed. 1105, the *Amos* court noted that that case was decided under the predecessor reissue statute which required reissue claims to be for the "same invention," and concluded that *U.S. Industrial* does not now mandate a separate "objective intent to claim" requirement. *Id.* The *Amos* court noted that this court reached the same conclusion eight years earlier in *Hounsfield*, 699 F.2d at 1323, 216 USPQ at 1047–48. *Id.*

Thus, the district court's conclusion that the "original patent" clause of § 251 was not satisfied based on an "objective intent to claim" requirement was in error. Stein does not contend that the test set forth in *Amos* for the "original patent" clause—*i.e.*, whether one skilled in the art would identify the subject matter of the reissue claims as invented and disclosed by the patentee—is not met by the asserted reissue claims. Rather, Stein relies entirely on its assertion that there is an "objective intent to claim" requirement and that that requirement is not met. However, we need not resolve this issue further, having already concluded that the asserted reissue claims are invalid for failing to meet the "error" requirement of § 251.

III

[15] Finally, Stein presents to us the question of whether the district court properly construed the claim term "high humidity steam." It is not immediately apparent whether this issue is properly before us. The district court did not construe the term in conjunction with a final judgment, such as a summary judgment of noninfringement or invalidity. Rather, the district court issued an oral ruling on the matter in preparation for trial. However, the district court having held the asserted claims invalid on summary judgment, which we here affirm, there can be no question of liability and hence the claim construction issue is moot. Therefore, we need not decide whether Stein's appeal of the claim construction is proper, and if so, whether the district court's construction was correct.

CONCLUSION

We affirm the grant of summary judgment of invalidity of the asserted reissue claims for failure to comply with 35 U.S.C. § 251 ¶ 1. Stein's cross-appeal is dismissed.

COSTS

Each party shall bear its own costs.

AFFIRMED.

APPENDIX 10

PROSECUTION AMENDMENT HISTORY OF CLAIMS OF INTEREST TO THIS APPEAL

Reproduced below is the prosecution amendment history of the claims of interest to this appeal, include broadest method of treatment claims presented during prosecution of the four patent applications leading to issuance of U.S. Patent No. 5,443,833 ("the original prosecution"), viz. original application claim 1, each of its amendments, cancellations and replacement claims; and pending reissue application claims 4-19.

1. Original Application (Serial No. 07/133,520)

On December 16, 1987, the '520 application was filed, with the broadest method of treatment claim, claim 1, reproduced as follows:[12]

[12] The reproductions in Appendix 10 are scanned images of the actual papers filed of the record on appeal.

- 18 -

Claims

1. A method of treatment of a disease selected from the group ~~comprising~~ consisting of:

conjunctivitis, keratitis, 'allergic eyes', adenovirus infections, corneal homograft rejection, anterior uveitis,

nasal polyps, vasomotor rhinitis, allergic manifestations of the nasopharynx,

reversible obstructive airways disease,

Crohn's disease, distal colitis and proctitis,

which method comprises administration to a patient suffering from such a condition of a therapeutically effective amount of an aqueous solution containing, as active ingredient, 9-ethyl-6,9-dihydro-4,6-dioxo-10-propyl-4H-pyrano(3,2-g)quinoline-2,8-dicarboxylic acid or a pharmaceutically acceptable salt thereof.

In an "Amendment A" received at the Patent Office on January 23, 1989, and that was in response to a rejection made under 35 U.S.C. § 112, ¶ 2 on the ground that claim 1 was presented in improper Markush form, claim 1 was amended to place it in proper Markush form, by replacing "comprising" with –consisting of--, as follows:

PATENT

IN THE UNITED STATES PATENT
AND TRADEMARK OFFICE

Applicant:	I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on this Date:
ANDREW R. CLARK ET AL.	
Serial No.: 133,520	
Filed: December 16, 1987	
For: PHARMACEUTICAL COMPOSITIONS	January 18, 1989 Date
	Basil P. Mann
Group Art Unit: 115	Registration No.: 18,464
Examiner: K. Markowski	Attorney for Applicant(s)

AMENDMENT "A"

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

In response to the Office Action dated July 20, 1988, please amend the above-identified application as follows:

IN THE CLAIMS

Claim 1, line 2, cancel "comprising" and insert --consisting of--.

This above amendment was entered, as indicated by handwritten annotation shown in the reproduction of claim 1, above. On April 4, 1989, this amended claim 1 was finally rejected in the original '520 application.

2. 1st Continuation Application (Serial No. 07/410,020)

After final rejection of all of its claims, the '520 application was abandoned in favor of the 1st continuation application, Serial No. 07/410,020, filed September 20, 1989. On September 10, 1990, in reply to an Office Action dated March 8, 1990, an "Amendment A" was submitted. Claim 1 was amended by deleting all recitations of eye, nasal

and colon diseases. The stated reason for this amendment was to more clearly focus the patentability issues related to the rejection and treatment of reversible obstructive airways disease. This amendment [brackets indicating claim terms that were deleted] to claim 1 was entered into the application, and is reproduced below.

Applicant:

ANDREW R. CLARK ET AL.

Serial No.: 07/410,020

Filed: September 20, 1989

For: PHARMACEUTICAL COMPOSITIONS

Group Art Unit: 115

Examiner: K. Markowski

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on this Date:

September 10, 1990
Date

Basil P. Mann
Registration No.: 18,464

Attorney for Applicant(s)

AMENDMENT "A"

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

In response to the Office Action of March 8, 1990, please amend the above-identified application as follows:

IN THE CLAIMS

Rewrite claim 1 as follows:

--1. (Amended) [A method of treatment of [a disease selected from the group consisting of:

conjunctivitis, keratitis, "allergic eyes," adenovirus infections, corneal homograft rejection, anterior uveitis,

nasal polyps, vasomotor rhinitis, allergic manifestations of the nasopharynx,]

reversible obstructive airways disease,

[Crohn's disease, distal colitis and proctitis,] which method comprises administration to a patient suffering from such a condition of a therapeutically effective amount of an aqueous solution containing, as active ingredient, the disodium salt of 9-ethyl-6,9-dihydro-4,6-dioxo-10-propyl-4H-pyrano(3,2-g)quinoline-2,8-dicarboxylic acid [or a pharmaecutically acceptable salt thereof].--

In an Office Action dated December 10, 1990, this amended claim 1 was finally rejected. Next, in a proposed "Amendment B" mailed to the Patent Office on June 10, 1991, an attempt was made to cancel claim 1 and replace it with a new, "first" claim 18. The examiner refused to enter Amendment "B" into the '020 application. This proposed-but-not-entered first claim 18 is reproduced below, as follows:

Add the following claims.

--18. A method of treatment of a disease selecte from the group consisting of conjunctivitis, keratitis, "allergic eyes," adenovirus infections, corneal homograft rejection, anterior uveitis, nasal polyps, vasomotor rhinitis, allergic manifestations of the nasopharynx, reversible obstructive airways disease, Crohn's disease, distal colitis and proctitis, which method comprises administering to a patient suffering from such a condition the contents of a soft ampoule of carbon dioxide permeable plastics material sterile-filled with a unit dose of an aqueous solution containing, as active ingredient, the disodium salt of 9-ethyl-6,9-dihydro-4,6-dioxo-10-propyl-4H-pyrano(3,2-g)quinoline-2,8-dicarboxylic acid, and sealed, the solution having a pH of 3.5 to 6.0, as defined in claim 7.

Proposed first claim 18 re-introduced into the broadest method of treatment claim the eye disease, the nasal disease, and the colon disease aspect of the claim. This proposed first claim 18 also narrowed the scope of protection regarding the administration of the active ingredient aspect of the claim by limiting administration to soft, carbon dioxide permeable, sealed plastic ampoules sterile-filled with a unit dose of the disodium salt of the active ingredient in a solution with a pH of 3.5 to 6.0. This proposed, first claim 18 was never part of the application that was examined on the merits.

3. 2nd Continuation Application (Serial No. 07/742,574)

The '020 application was abandoned in favor of a second continuation application, Serial No. 07/742,574, filed on August 7,1991. In a preliminary amendment filed with the application, claim 1 was cancelled and a second claim 18 ("second claim 18") was proposed and added to the application. This second claim 18 was identical to the first, not entered claim 18 in the parent '020 application, except that (i) it required a container rather than a "soft" ampoule; (ii) it required the container to be "sterile-filled" with a "pharmaceutical solution;" and (iii) it broadened the form of the active ingredient to include not only the "disodium salt" form but also to include the --acid or a pharmaceutically acceptable salt thereof--form. The second claim 18, which was entered into the application, is reproduced below (as further amended with handwritten annotations):

Add the following claims:

--18. A method of treatment of a disease selected from the group consisting of conjunctivitis, keratitis, "allergic eyes," adenovirus infections, corneal homograft rejection, anterior uveitis, nasal polyps, vasomotor rhinitis, allergic manifestations of the nasopharynx, reversible obstructive airways disease, Crohn's disease, distal colitis and proctitis, which method comprises administering to a patient suffering from such a condition the contents of ~~a container~~ an ampoule of carbon dioxide permeable plastics material filled with a unit dose of an aqueous pharmaceutical solution containing, as active ingredient, 9-ethyl-6,9-dihydro-4,6-dioxo-10-propyl-4H-pyrano(3,2-g)quinoline-2,8-dicarboxylic acid or a pharmaceutically acceptable salt thereof, and sealed, the solution having a pH of 3.5 to 6.0, as defined in claim 7.

Next, in another Amendment "A", received in the Patent Office Mail Room on October 13, 1992, the second claim 18 was amended to replace "a container" with –an ampoule--. The relevant part of that Amendment "A" is reproduced below:

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

ANDREW R. CLARK ET AL.

Serial No. 07/742,574

Filed: August 7, 1991

For: PHARMACEUTICAL COMPOSITIONS

Group Art Unit: 1502

Examiner: W. Benston, Jr.

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on this date:

October 8, 1992

Basil P. Mann
Registration No. 18,464
Attorney for Applicant(s)

AMENDMENT "A"

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

In response to the Office Action of April 8, 1992, please amend the above-identified application as follows:

IN THE CLAIMS

Claim 7, lines 1 and 2; claim 10, lines 1 and 2; claims 17, lines 1 and 2; claim 18, line 9; claim 20, line 1; and claim 22, line 1, cancel "A container" and insert --An ampoule--.

The '574 application claim 18 was finally rejected on November 10, 1992. Subsequently, in an Amendment "B" After Final Rejection, received at the Patent Office Mail Room on May 12, 1993, applicants proposed to further amend the second claim 18 to require that the solution be a "pharmaceutical" solution. The relevant part of this Amendment "B" is reproduced below.

RESPONSE UNDER 37 CFR 1.116
EXPEDITED PROCEDURE
EXAMINING GROUP 1502

PATENT APPLICATION

IN THE UNITED STATES PATENT
AND TRADEMARK OFFICE

Applicant:
ANDREW R. CLARK ET AL.

Serial No. 07/742,574

Filed: August 7, 1991

For:
PHARMACEUTICAL COMPOSITIONS

Group Art Unit: 1502

Examiner: W. Benston, Jr.

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on this date:

May 10, 1993

Basil P. Mann
Registration No. 18,464
Attorney for Applicant(s)

AMENDMENT "B" AFTER FINAL REJECTION

BOX AF
Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

In response to the Office Action of November 10, 1992, please amend the above-identified application as follows:

IN THE CLAIMS

Claim 18, line 10, after "aqueous" insert --pharmaceutical--.

The examiner refused to enter this Amendment "B". The second claim 18 was finally rejected, with only the first amendment entered, and the 3rd continuation application was thereafter filed.

4. 3rd Continuation Application (Serial No. 08/82,804)

On June 25, 1993, the 3rd continuation application, Serial No. 08/82,804 was filed. Applicants requested that the amendment submitted after final rejection in the '574 application be entered in the 3rd continuation application. The examiner permitted the amendment to be entered, and this second claim 18, as amended, became the broadest claim directed to treatment of eye disease.

Next, in an Amendment "B" After Final under 37 C.F.R. § 1.116, received in the Patent Office Mail Room on February 16, 1995, the twice amended, second claim 18 was cancelled, and replaced with new claims 23-25, as follows:

Please add new claims 23-25 as follows:

--23. A method of treating a reversible obstructive airways disease comprising administering, by inhalation, to a patient suffering from, or susceptible to, such a condition the nebulized contents of an ampoule of carbon dioxide permeable plastics material filled with a unit dose of an aqueous pharmaceutical solution containing, as active ingredient, from 0.1 to 5% w/v of 9-ethyl-6,9-dihydro-4,6-dioxo-10-propyl-4H-pyrano(3,2-g)quinoline-2,8-dicarboxylic acid or a pharmaceutically acceptable salt thereof, the solution having a pH of 3.5 to 6.0.

24. The method of treatment according to claim 23, wherein the concentration of the active ingredient in the solution is from 0.1 to 1.0% w/v.

25. The method of treatment according to claim 23, wherein the active ingredient is nedocromil sodium.--

New claim 23 then became the broadest method of treatment claim, but was limited to a method of treating a reversible obstructive airways disease. These claims were allowed, renumbered and issued as claims 1-3 of the '833 patent.

5. Reissue Application (Serial No. 08/916,578)

On August 22, 1997, reissue application Serial No. 08/916,578 was filed with new independent claim 4 directed to a method of treatment of 4 types of eye diseases, and with new independent claim 10 directed to a method of controlling the symptoms of conjunctivitis, as follows:

4. A method of treatment of a disease selected from the group consisting of conjunctivitis, keratitis, "allergic eyes," and anterior uveitis, which method comprises administering to the eye an effective amount of an ophthalmically acceptable aqueous pharmaceutical solution containing an active ingredient 9-ethyl-6, -dihydro-4, 6-dioxo-10-propyl-4H-pyrano(3,2g)quinoline-2, 8-dicarboxylic acid, or a pharmaceutically acceptable salt thereof.

5. The method of claim 4, wherein the disease is conjunctivitis.

6. The method of claim 5, wherein the disease is seasonal allergic conjunctivitis.

7. The method of claim 5, wherein the disease is allergic conjunctivitis.

8. The method of claim 5, wherein the disease is vernal conjunctivitis.

9 The method of claims 4, 5, 6, 7 or 8, wherein said active ingredient is nedocromil sodium.

10. A method of controlling the symptoms of conjunctivitis comprising administering to the eye of a patient having conjunctivitis an effective amount of nedocromil sodium in an ophthalmically acceptable formulation.

11. The method of claim 10, wherein the conjunctivitis is vernal conjunctivitis.

12. The method of claim 10, wherein the conjunctivitis is allergic conjunctivitis.

13. The method of claim 10, wherein the conjunctivitis is seasonal allergic conjunctivitis.

In an amendment mailed July 9, 2001, claims 4-9 were cancelled, and replaced with new claims 14-19, the text of which is provided in Appendix 1.

APPENDIX 11

Reissue Claim 14 Scope Compared to Patent Claim 1 Scope

Limitation	Claim Limitation Scope Reissue Claim 14	Claim Limitation Scope '833 Patent Claim	Which Limitation is Broader?
1	Four types of eye disease	No eye disease	Reissue
2	Administration to eye	No administration to eye	Reissue
3	Any dose for which the specification provides support	Unit dose	Reissue
4	Any aqueous soluble solution for which the specification provides support	Nebulised solution	Reissue
5	Any container for which the specification provides support	Ampoule	Reissue
6	Container can be of any material for which the specification provides support	Plastics	Reissue
7	Any solubility for which the specification provides support	Carbon dioxide soluble	Reissue
8	Any weight to volume ratio for which the specification provides support	0.1 to 5% w/v	Reissue
9	Any pH for which the specification provides support	3.5 to 6.0	Reissue

APPENDIX 12

Mentor v. Coloplast, Inc.

MENTOR CORPORATION,
Plaintiff/Cross-Appellant,

v.

COLOPLAST, INC., Defendant-Appellant.

Nos. 92-1428, 92-1429.

United States Court of Appeals, Federal Circuit.

July 20, 1993.

Holder of patent for male condom catheter brought action against competitor alleging patent infringement. Competitor brought action for declaration of invalidity, unenforceability and noninfringement. Cases were consolidated. The United States District Court for the Middle District of Florida, Anne C. Conway, J., entered judgment against competitor but found that competitor did not act willfully. Cross appeals were taken. The Court of Appeals, Lourie, Circuit Judge, held that: (1) patent holder's claims of reissue patent for male condom catheter were invalid as not being based on "error" within meaning of reissue statute, and (2) competitor's patent did not infringe on holder's patent.

Affirmed in part, reversed in part, and vacated in part.

1. Patents ⇐136

Claims of reissue patent for male condom catheter were invalid as not being based on "error" within meaning of reissue statute; patent holder deliberately and intentionally amended its claims in response to prior art rejection and that conduct was not reissuable error. 35 U.S.C.A. § 251.

2. Federal Courts ⇐776

Whether statutory requirement of "error" for reissue of defective patent has been met is an issue of law which Court of Appeals reviews de novo; legal conclusion is based on underlying factual inquiries which are reviewed for substantial evidence. 35 U.S.C.A. § 251.

3. Patents ⇐134

"Error" required for reissue of defective patent is generally liberally construed. 35 U.S.C.A. § 251.

4. Patents ⇐134

Procedure for reissue of defective patent does not give patentee a second opportunity to prosecute de novo his original application. 35 U.S.C.A. § 251.

5. Patents ⇐141(6)

If patentee tries to recapture what he or she previously surrendered to obtain allowance of original patent claims, that deliberate withdrawal or amendment cannot be said to involve inadvertence or mistake contemplated by statute governing reissue of defective patents and is not an error of kind which will justify granting of reissue patent which includes the matter withdrawn. 35 U.S.C.A. § 251.

6. Patents ⇐109

Recapture rule does not apply where there is no evidence that amendment of originally filed claims was in any sense an admission that scope of that claim was not in fact patentable.

7. Patents ⇐141(6)

Error under reissue statute does not include deliberate decision to surrender specific subject matter to overcome prior art, a decision which in light of subsequent developments in marketplace might be regretted. 35 U.S.C.A. § 251.

8. Patents ⇐141(6, 7)

Reissue claims that are broader in certain respects and narrower in others may avoid effect of recapture rule.

9. Patents ⇐141(6)

If reissue claim is broader in a way that does not attempt to reclaim what was surrendered earlier, recapture rule may not apply.

10. Federal Courts ⇐776

Patent claim construction is an issue of law which Court of Appeals reviews de novo.

11. Patents ⇐234

Male condom catheter which excluded transfer of adhesive from outer to inner sur-

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to inside upon ro

William L. Antl
& Harrison, of I
plaintiff/cross-app
brief was Robert
Voorhis & Wells,
counsel was Robe

Edward A. M
Gerb & Soffen, of
defendant-appellar
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III.

Before LOURI
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face did infringe on catheter in which adhesive was transferred from outside of catheter to inside upon rolling and unrolling.

William L. Anthony, Jr., Brobeck, Phleger & Harrison, of Palo Alto, CA, argued for plaintiff/cross-appellant. With him on the brief was Robert W. Duckworth, Maguire, Voorhis & Wells, P.A., of Orlando, FL. Of counsel was Robert L. Walter.

Edward A. Meilman, Ostrolenk, Faber, Gerb & Soffen, of New York City, argued for defendant-appellant. With him on the brief were Marvin C. Soffen and William O. Gray, III.

Before LOURIE, CLEVENGER, and SCHALL, Circuit Judges.

LOURIE, Circuit Judge.

This is an appeal and cross-appeal from the April 7, 1992 judgment of the United States District Court for the Middle District of Florida, *Mentor Corp. v. Coloplast, Inc.*, Case Nos. 89-954-Civ-T-22A, 90-528-Civ-T-22A (M.D.Fla.1992). Following a March 1992 jury verdict, judgment was entered against Coloplast, Inc., holding, *inter alia*, that all the original and reissued claims of Mentor Corporation's U.S. Patent Re. 33,206 were willfully infringed, that the '206 patent was not invalid, and that Coloplast was liable for $250,000 in damages. The district court subsequently granted Coloplast's motion for judgment as a matter of law that willfulness was not shown, and denied its motion in all other respects. Coloplast appeals on the issues of validity and infringement. Mentor cross-appeals on the issue of willfulness. We affirm-in-part, reverse-in-part, and vacate-in-part.

BACKGROUND

In July 1989, Mentor sued Coloplast for infringement of U.S. Patent 4,475,910, entitled "Male Condom Catheter Having Adhesive on Rolled Portion." While the lawsuit was pending, it was reissued as the '206 patent and Coloplast filed a separate suit for a declaration of invalidity, unenforceability, and noninfringement of that patent. Mentor amended its complaint in the original action to allege infringement of the '206 patent and the two cases were consolidated.

The claimed invention relates to a condom catheter which is used on male patients suffering from incontinence. Claims 1–4 of the '206 patent recite a catheter having a pressure sensitive adhesive on a non-stick (release) layer located on the outer surface of a condom sheath prior to it being rolled up, such that on rolling the sheath outwardly, the adhesive on the outer surface comes into contact with and sticks to the inner surface. When unrolled, the adhesive which was initially applied to the release layer on the outer surface is thereby transferred to the inner surface. Claim 1, from which claims 2–4 depend, reads:

> A male condom catheter designed to be connected to a urine collection means and comprising a thin cylindrical sheath member of resilient material rolled outwardly upon itself to form consecutively larger rolls, said sheath member having an outer surface and an inner surface designed to engage a penis when the catheter is unrolled, and the outer surface of the sheath member having prior to the rolling thereof a layer of pressure sensitive adhesive over a substantial portion thereof with a release layer between said adhesive and the outer surface of the sheath member so that as the sheath member is rolled up the pressure sensitive adhesive on the outer surface is in direct contact with the inner surface of an adjacent roll so that *as the sheath member is unrolled the adhesive on the outer surface is transferred to the portion of the inner surface in engagement with the outer surface*, without rolling the catheter inside out, to cause the inner surface to adhere to the penis over which the sheath is placed.

(Emphasis added.)

Claims 6–9, which were added during reissue, do not recite the transfer of adhesive from the outer to the inner surface of the catheter. They read as follows:

> 6. A male condom catheter to be adhesively secured to a penis and designed to be connected to a urine collection means, said catheter comprising a thin, flexible

cylindrical member of resilient material rolled outwardly upon itself to form a single roll with consecutively larger turns, the outer surface of the cylindrical member having an adhesive release layer thereon and said turns having a layer of pressure sensitive adhesive therebetween in contact with the inner surface of the cylindrical member and in contact with the release layer so that upon said cylindrical member being unrolled onto a penis, the adhesive releases from the adhesive release layer due to the unrolling of the cylindrical member and adheres only to the inner surface of the cylindrical member to cause the cylindrical member to adhere to the penis.

7. The catheter of claim 6 in which the adhesive release layer and the adhesive extend over at least one turn of the roll.

8. The catheter of claim 6 in which there is a bulbous surge chamber secured to the outlet side of the cylindrical member.

9. The catheter of claim 6 in which the adhesive release layer is formed of silicon rubber.

Coloplast sells the Coloplast Self Sealing Urosheath, which is made by applying adhesive directly to the inner surface, the outer surface being coated with a non-stick, release layer. Use of the Coloplast device does not involve the transfer of adhesive from the outer to the inner surface. Coloplast admitted that its device was covered by broadened reissue claims 6–9, but asserted that it had acquired intervening rights and, in any event, that the claims were invalid.

The district court entered judgment according to the jury's answers to special interrogatories, finding, inter alia, that Coloplast infringed claims 1–4 of the '206 patent by the sale of the Coloplast Urosheath, that Coloplast had willfully infringed the '206 patent, that Mentor's broadened reissue claims 6–9 did not recapture any subject matter deliberately cancelled by Mentor, and that Coloplast had not acquired intervening rights with respect to claims 6–9. Following Coloplast's post-trial motion for judgment as a matter of law, the court upheld the jury's finding of infringement, but set aside the finding of willfulness.

DISCUSSION

[1] On appeal of a judgment entered on a verdict after denial of a motion for judgment as a matter of law under Fed.R.Civ.P. 50(b), Coloplast must show

> (1) that reasonable persons could not in light of . . . evidence [before them] have found the facts necessary to support the jury's verdict; *or* (2) that the facts properly found cannot in law support that verdict.

Railroad Dynamics, Inc. v. A. Stucki Co., 727 F.2d 1506, 1513, 220 USPQ 929, 936 (Fed.Cir.), *cert. denied*, 469 U.S. 871, 105 S.Ct. 220, 83 L.Ed.2d 150 (1984).

Coloplast argues that claims 6–9 of the reissue patent are invalid because they are not based on "error" within the meaning of 35 U.S.C. § 251 (1988). Coloplast argues that Mentor deliberately and intentionally amended its claims in response to a prior art rejection and that such conduct is not reissuable error. Thus, it asserts, the court erred as a matter of law. We agree.

[2] Whether the statutory requirement of "error" has been met is an issue of law which we review de novo. This legal conclusion is based on underlying factual inquiries which are reviewed for substantial evidence. *See Ball Corp. v. United States*, 729 F.2d 1429, 1439, 221 USPQ 289, 297 (Fed.Cir.1984) ("On the basis of the facts before us and the reasons given for the cancellation of the claims from the original application, we cannot find, as a matter of law, that [the patentee] is barred from securing reissue . . ."):

> Section 251 provides in pertinent part:
>
> Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Commissioner shall . . . reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent.

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In re Willing
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[3, 4] Reissue "error" is generally liberally construed, and we have recognized that "[a]n attorney's failure to appreciate the full scope of the invention" is not an uncommon defect in claiming an invention. *In re Wilder*, 736 F.2d 1516, 1519, 222 USPQ 369, 371 (Fed.Cir.1984), *cert. denied*, 469 U.S. 1209, 105 S.Ct. 1173, 84 L.Ed.2d 323 (1985). However, the reissue procedure does not give the patentee "a second opportunity to prosecute *de novo* his original application," *In re Weiler*, 790 F.2d 1576, 1582, 229 USPQ 673, 677 (Fed.Cir.1986).

> The deliberate cancellation of a claim of an original application in order to secure a patent cannot ordinarily be said to be an "error" and will in most cases prevent the applicant from obtaining the cancelled claim by reissue. The extent to which it may also prevent him from obtaining other claims differing in form or substance from that cancelled necessarily depends upon the facts in each case and particularly on the reasons for the cancellation.

In re Willingham, 282 F.2d 353, 357, 127 USPQ 211, 215 (CCPA 1960).

[5, 6] If a patentee tries to recapture what he or she previously surrendered in order to obtain allowance of original patent claims, that "deliberate withdrawal or amendment . . . cannot be said to involve the inadvertence or mistake contemplated by 35 U.S.C. § 251, and is not an error of the kind which will justify the granting of a reissue patent which includes the matter withdrawn." *Haliczer v. United States*, 356 F.2d 541, 545, 148 USPQ 565, 569 (Ct.Cl.1966). "The recapture rule bars the patentee from acquiring, through reissue, claims that are of the *same* or of *broader scope* than those claims that were cancelled from the original application." *Ball Corp.*, 729 F.2d at 1436, 221 USPQ at 295 (citations omitted). The recapture rule does not apply where there is no evidence that amendment of the originally filed claims was in any sense an admission that the scope of that claim was not in fact patentable, *Seattle Box Co. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 826, 221 USPQ 568, 574 (Fed.Cir.1984), but that is not the situation here.

During prosecution of the original patent application, the examiner rejected claim 1 as unpatentable over U.S. Patent 4,187,851 to Hauser in view of U.S. Patent 2,389,831 to Welsh and U.S. Patent 3,403,682 to McDonell. According to the examiner, Hauser lacked the positioning of an adhesive means between the rolls, which was taught by Welsh and McDonell. Mentor responded by replacing claim 1, which did not require "transfer" of adhesive from an outer layer to an inner layer, with a new claim 7, which read in part as follows:

> A male condom catheter . . . comprising a thin cylindrical sheath member . . . having an outer surface and an inner surface . . . and the outer surface of the sheath member having a layer of pressure sensitive adhesive over a substantial portion thereof with a release layer between said adhesive and the outer surface of the sheath member so that as the sheath member is unrolled the adhesive on the outer surface *is transferred* to the porton [sic] of the inner surface in engagement with the outer surface to cause the inner surface to adhere to the penis over which the sheath is placed.

(Emphasis added.)

The claims were again rejected under 35 U.S.C. § 103 as unpatentable over McDonell in view of Welsh. The examiner stated that McDonell disclosed a male catheter with a sheath having an outer surface with adhesive and a release layer, and that Welsh showed a sheath with adhesive, which when unrolled was transferred from the outer surface to the inner surface. In response, Mentor further amended claim 7 to recite that as the sheath member is

> rolled up the pressure sensitive adhesive on the outer surface is in direct contact with the inner surface of an adjacent roll so that as the sheath member is unrolled, the adhesive on the outer surface *is transferred without rolling the catheter inside out*. . . .

(Emphasis added.) Mentor argued that "none of the references relied upon actually showed the *transfer of adhesive* from the outer surface to the inner surface as the sheath is rolled up and then unrolled." Men-

tor characterized the prior art references as disclosing the "transfer" of adhesive from the outer to the inner surface solely by turning the sheath inside out so that the outer surface becomes the inner surface and the adhesive always remains on the same surface. Amended claim 7 then issued as claim 1 as a result of Mentor's amendments and argument.

Within two years of issuance, Mentor filed a reissue application accompanied by an attorney declaration, stating that Mentor claimed less than it had a right to claim because the claims of the '910 patent did not "read literally upon male external catheters manufactured using a process in which the adhesive is applied to the inner latex surface of the sheath at the time of manufacture, before the device was rolled." The declaration further stated that "[t]he error arose because [the attorney] assumed that the manufacture of male external catheters by applying the adhesive to the inner latex surface of the catheter was too impractical to be commercially feasible. . . ." Mentor thus added new claims lacking the requirement of transfer of adhesive from the outer to the inner layer. The examiner rejected the claims as obvious over McDonell in view of Welsh. After Mentor submitted detailed information on commercial success, the examiner allowed the claims and the patent was reissued with original claims 1–4 and new claims 6–9.

Coloplast correctly argues that reissue claim 6, which does not include the adhesive transfer limitation, impermissibly recaptures what Mentor deliberately surrendered in the original prosecution. Specifically, the reissue claims do not contain the limitation that, during rolling and unrolling, the adhesive be transferred from the outer to the inner surface of the catheter.

[7] Error under the reissue statute does not include a deliberate decision to surrender specific subject matter in order to overcome prior art, a decision which in light of subsequent developments in the marketplace might be regretted. It is precisely because the patentee amended his claims to overcome prior art that a member of the public is entitled to occupy the space abandoned by the patent applicant. Thus, the reissue statute cannot be construed in such a way that competitors, properly relying on prosecution history, become patent infringers when they do so. In this case, Mentor narrowed its claims for the purpose of obtaining allowance in the original prosecution and it is now precluded from recapturing what it earlier conceded.

Mentor argues that the reissue claims do not recapture subject matter surrendered during the original prosecution. Mentor specifically alleges that recapture is avoided because newly-added reissue claims 6–9 are materially narrower in some respects, albeit broader in others.

[8, 9] Reissue claims that are broader in certain respects and narrower in others may avoid the effect of the recapture rule. If a reissue claim is broader in a way that does not attempt to reclaim what was surrendered earlier, the recapture rule may not apply. However, in this case, the reissue claims are broader than the original patent claims in a manner directly pertinent to the subject matter surrendered during prosecution. Mentor thus attempted to reclaim what it earlier gave up. Moreover, the added limitations do not narrow the claims in any material respect compared with their broadening.

The limitation in claim 6 that the catheter material be "flexible" did not materially narrow the claims, which already recited that the material be "resilient." Likewise, the limitation that the catheter be rolled outward to form a "single" roll did not materially limit the claims; the catheter can only be rolled and applied from a single end to form a single roll when the other end is connected to a urine collection means. Further, the addition of the words "thereon," referring to the location of the adhesive release layer on the outer surface prior to unrolling, and "only," referring to the adhering of the adhesive to the inner surface after unrolling, did not materially narrow the claims.

Additionally, claims 7–9, which depend from claim 6, do not avoid recapture because they do not add any limitations, material in relation to the impermissible broadening, that distinguish them over claim 6, which we

have determined is not a proper subject for reissue. Reissue claim 7, which requires adhesive on "at least one turn of the roll," is not materially narrower than original claim 7, the subject matter of which was partially surrendered. Reissue claim 8 recites a bulbous surge chamber, which was already in the prior art. Reissue claim 9, which recites the material of the adhesive release layer, does not materially narrow the claim. Accordingly, they do not avoid recapture.

Thus, since none of reissue claims 6–9 meets the legal requirements for reissue, the court erred in denying the motion for judgment of invalidity as a matter of law. We therefore reverse that part of the court's judgment finding claims 6–9 not invalid. At this stage of the proceedings, we need not reach the issue of infringement of the reissue claims in light of our conclusion regarding their invalidity. We thus vacate the holding on infringement of claims 6–9.

[10] Coloplast also argues that it did not infringe claims 1–4 of the Mentor patent as a matter of law. We agree. Neither party disputes the structure of the Coloplast device or how it is used. The parties only dispute the proper scope of the claims. Claim construction is an issue of law which we review de novo. *ZMI Corp. v. Cardiac Resuscitator Corp.*, 844 F.2d 1576, 1578, 6 USPQ2d 1557, 1559 (Fed.Cir.1988). Mentor argues that claims 1–4 are product-by-process claims and that, under *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 1001 (Fed.Cir.1991), the process limitations do not prevent the claims from encompassing an identical product made by a different process. Mentor's argument, however, is inapplicable to the present case. The claims in issue here are not in fact product-by-process claims; product-by-process claims recite how a product is made, not how it is used. The only process aspect of the present claims relates to how the product is used, and that is an essential aspect of the claims.

[11] Claims 1–4 recite a catheter in which the adhesive is transferred from the outside of the catheter to the inside upon rolling and unrolling. Neither party disputes that Coloplast's device excludes the transfer of adhesive from the outer to inner surface. Thus, as a matter of law, Coloplast's device cannot infringe those claims, and no reasonable juror could have found otherwise. The court therefore erred in denying Coloplast's motion for judgment of noninfringement as a matter of law.

Because of our disposition on the issues of infringement and validity, we do not address Mentor's cross-appeal on willfulness. We affirm the judgment in all other respects.

CONCLUSION

We reverse the district court's decision denying the motion for judgment as a matter of law concerning noninfringement of claims 1–4 and invalidity of claims 6–9. We vacate the court's judgment with respect to infringement of claims 6–9. We affirm the judgment in all other respects.

COSTS

Costs to Coloplast.

AFFIRMED-IN-PART, REVERSED-IN-PART, AND VACATED-IN-PART.

WEST KEY NUMBER SYSTEM

Harry R. RICE, Petitioner,
v.
DEPARTMENT OF the TREASURY, Respondent.

No. 93-3059.

United States Court of Appeals, Federal Circuit.

July 22, 1993.

Rehearing Denied Aug. 30, 1993.

Supervisory Internal Revenue agent appealed from a decision of the Merit Systems Protection Board, 55 M.S.P.R. 279, affirming his removal from his position by the Internal Revenue Service. The Court of Appeals, Skelton, Senior Circuit Judge, held that: (1)

APPENDIX 13

Seattle Box v. Industrial Crating

statement of reasons, which we find sufficient. No further discussion on the merits of these claims is necessary here.

Our decision as to these claims, however, is only with respect to the subcontractors' actions *against* the government. Several of the claims raise questions of improper acts done by the government in conjunction with Erickson; the subcontractors, therefore, may yet have valid actions against Erickson. We do not intend our decision here to imply that we have made any judgment as to the merit of similar actions between Erickson and its subcontractors.

IV

Conclusion

The decision of the Department of Energy Board of Contract Appeals is affirmed.

AFFIRMED.

SEATTLE BOX COMPANY, INC., d/b/a Seattle-Tacoma Box Company, Appellee,

v.

INDUSTRIAL CRATING & PACKING, INC., and James F. Rennels, Appellants.

Appeal No. 83-890.

United States Court of Appeals, Federal Circuit.

March 26, 1984.

Appeal was taken from a judgment of the United States District Court for the Western District of Washington, Lloyd Shorett, Special Master, which held patent No. Re. 30,373 for shipping bundles for pipe lengths valid and infringed. The Court of Appeals, Nichols, Senior Circuit Judge, held that: (1) the patent was valid; (2) plaintiff could not recover damages for any activities performed before its new and broadened claims issued in the reissue patent; (3) case would be remanded for determination of whether quarter-inch short spacer blocks literally infringed claims in issue; and (4) since plaintiff repeated no claim from its original patent in its reissue patent, defendant in patent infringement suit could properly raise defense of intervening rights.

Affirmed in part, reversed in part, vacated in part and remanded.

1. Patents ⇐16(1)

Fact findings to be made in connection with determining whether a patent is invalid for obviousness are: determination of the scope and content of the prior art; ascertainment of the differences between the prior art and the claims at issue; and the resolution of the level of ordinary skill in the pertinent art. 35 U.S.C.A. § 103.

2. Patents ⇐324.55(2)

Reviewing court will not set aside fact findings made in connection with determination of whether a patent is invalid for obviousness unless such findings are clearly erroneous. 35 U.S.C.A. § 103; Fed. Rules Civ.Proc.Rule 52(a), 28 U.S.C.A.

3. Patents ⇐16.31

Patent No. Re. 30,373 for shipping bundles for pipe length was not invalid for obviousness. 35 U.S.C.A. § 103.

4. Patents ⇐324.5

Court of Appeals does not consider evidence in patent cases de novo.

5. Patents ⇐101(6)

Patent No. Re. 30,373 for shipping bundles for pipe lengths was not invalid for indefiniteness. 35 U.S.C.A. § 112.

6. Patents ⇐109

Recapture rule did not apply where there was no evidence that assignee of patent rights amendment of its originally filed claims was in any sense an admission

that the scope of that claim was not in fact patentable.

7. Patents ⇐148

An original patent cannot be infringed once a reissue patent has been issued since the original patent is surrendered.

8. Patents ⇐141(4)

Plaintiff, in broadening its claims' scope to cover not only spacer blocks "greater than" but also "substantially equal to" diameter of pipes in a bundle made substantive change to its claims issue in its reissue patent for shipping bundles for pipe lengths; thus, plaintiff could not recover damages for any activities performed before its new and broadened claims issued in the reissue patent. 35 U.S.C.A. § 252.

9. Patents ⇐324.60

Case would be remanded for determination of whether quarter-inch short spacer blocks literally infringed claims in reissue patent for shipping bundles for pipe lengths.

10. Patents ⇐237

Doctrine of equivalents only comes into play when there is not literal infringement.

11. Patents ⇐148

Plaintiff's statement during its prosecution of reissue patent estopped it from asserting that its claims had a broad effect under doctrine of equivalents.

12. Patents ⇐144

When a reissue patent issues, a new patent with presumably valid claims exists.

13. Patents ⇐138(2)

If valid claims in original patent appear unaltered in reissue patent, doctrine of intervening rights affords no protection to the alleged infringer. 35 U.S.C.A. § 252.

14. Patents ⇐138(2)

Since plaintiff repeated no claim from its original patent in its reissue patent, defendant in patent infringement suit could properly raise defense of intervening rights. 35 U.S.C.A. § 252.

15. Patents ⇐138(2)

When doctrine of intervening rights is properly raised, court must consider whether to use its broad equity powers to fashion an appropriate remedy. 35 U.S.C.A. § 252.

Richard W. Seed, Seattle, Wash., argued for appellants. With him on brief was B.F. Berry, Seattle, Wash.

F.A. Utecht, Long Beach, Cal., argued for appellee. With him on brief were Ford E. Smith and David L. Garrison, Seattle, Wash.

Before DAVIS, Circuit Judge, NICHOLS, Senior Circuit Judge, and BALDWIN, Circuit Judge.

NICHOLS, Senior Circuit Judge.

This appeal is from a judgment of the United States District Court for the Western District of Washington, holding United States Patent No. Re. 30,373 valid and infringed, 217 USPQ 343 (W.D.Wash.1982), granting a permanent injunction, and awarding damages. We *affirm in part, reverse in part, vacate in part,* and *remand.*

I

Background

Plaintiff-appellee Seattle Box Company, Inc. ("Seattle Box") and defendant-appellant Industrial Crating and Packing, Inc. ("Industrial") are Washington State corporations which provide oil pipe bundling services to oil companies. Both corporations have their principal places of business in Washington State.

Seattle Box filed this action on July 2, 1980, alleging that Industrial infringed U.S. Patent No. 4,099,617 ("the '617 patent") entitled "Shipping Bundle for Numerous Pipe Lengths." Seattle Box brought the action in its capacity as assignee of the rights in the '617 patent. On August 19, 1980, the United States Patent and Trade-

mark Office ("PTO") reissued the '617 patent, with broadened claims, in U.S. Patent No. Re. 30,373 ("the '373 reissue patent"). Seattle Box also was the assignee of the rights in this patent. On October 10, 1980, Seattle Box amended its complaint to allege infringement of the '373 reissue patent. Industrial answered and counterclaimed, alleging patent invalidity, noninfringement, and patent misuse.

The district court held in favor of Seattle Box on May 4, 1982, and after an accounting for damages, entered judgment on February 9, 1983. Industrial presses only the issues of patent invalidity and noninfringement here on appeal.

A. *The Invention*

Until at least 1975, oil companies commonly transported oil pipes of various diameters and with weights upwards of 40 pounds per foot, as loose joints about 40 feet in length. Since no packaging procedure capable of safely and securely handling oil country pipe then existed, many pipes were irreparably damaged in transit and during loading and unloading operations. Rennels, a representative for Atlantic Richfield Company ("ARCO"), in late 1975 recognized ARCO's pipe transport problems and discussed with the patentee, Ferdinand J. Nist, Jr. ("Nist"), ARCO's need for a pipe bundling method which would get oil pipe to the Alaskan North Slope without bends, dents, or damaged ends. Although at the time of this discussion Nist had no experience in packaging oil pipes, he nevertheless undertook the project.

After extensive experimentation, which the district court opinion sets forth in great detail, Nist settled on a system in which he placed a tier of pipes across parallel horizontal wooden beams, or "sleepers." To ensure that adjacent pipes remained separated, Nist placed between them a double-concave wooden spacer block, depicted in Figure 1.

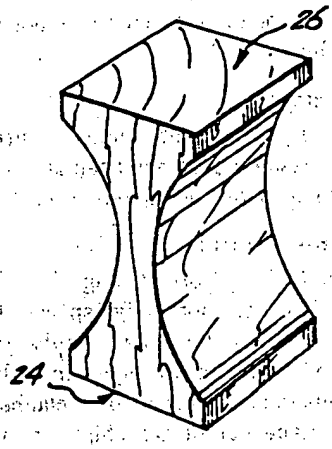


Figure 1

Nist stacked several tiers of these crossing rows of sleepers and pipes in order to make one pipe bundle. To prevent the weight of the upper pipes from crushing the lower pipes in either a bundle or a stack of bundles, Nist made his spacer blocks with a height at least equal to the pipe's diameter; the spacer blocks, therefore, absorbed most of the weight of the overhead load.

Figures 2–4 below depict a pipe bundle made according to the Nist method. In these figures, pipes 18, 36, and 44 lie across wooden sleepers 10, 30, 40, and 50. Double-concave spacers 22 separate the pipe. Finally, strapping materials 38, 46, 52, 59, and 60 hold together the entire bundle.

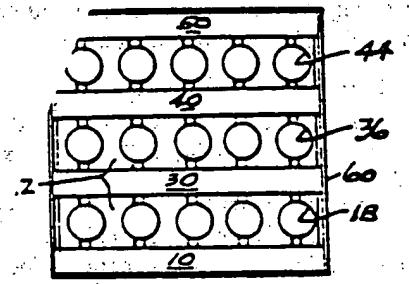


Figure 2

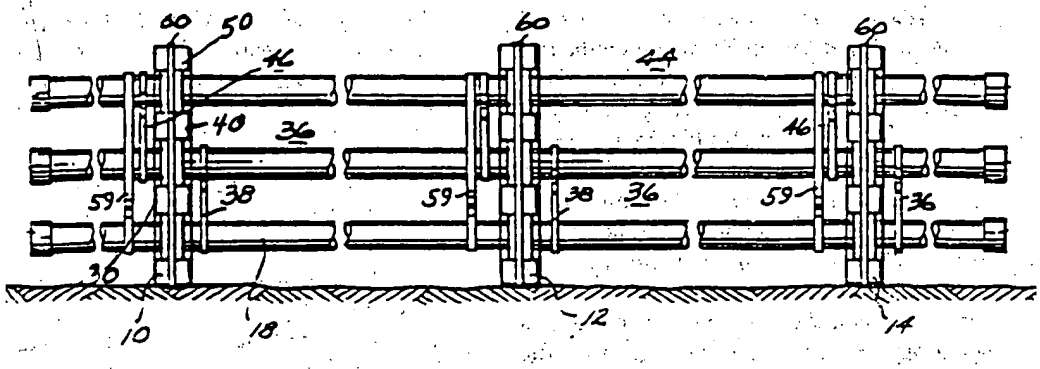


Figure 3

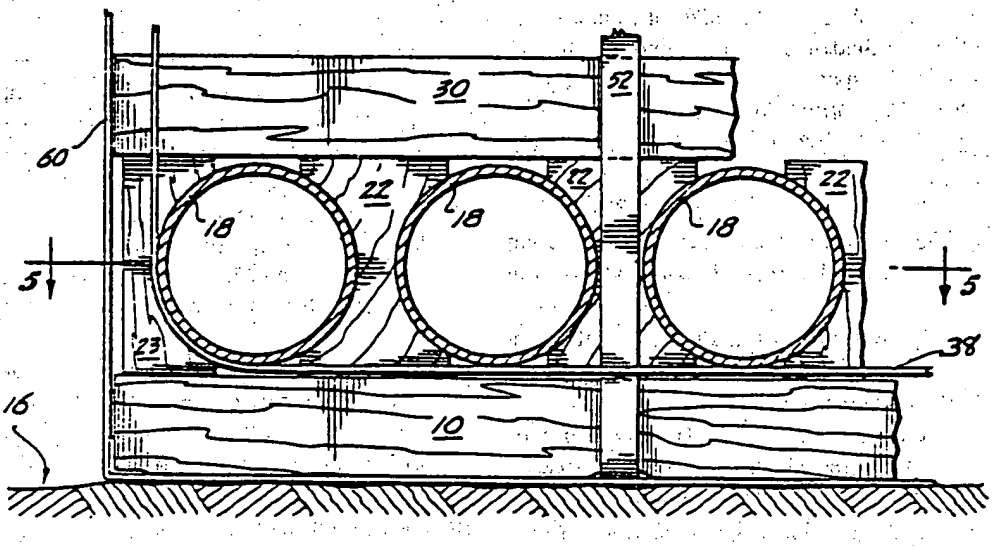


Figure 4

B. *The Patent*

Seattle Box filed an application for a patent on Nist's invention on February 17, 1977. Claim 1 of this application stated that the double-concave spacer block had a "height substantially equal to the thickness of the tier of pipe lengths."

Seattle Box's patent attorney, however, narrowed Claim 1 during the application's prosecution so as to specify that the spacer block had a height only "greater than the diameter of the pipe." Soon after the attorney made this narrowing amendment, although not necessarily because of it, the patent examiner allowed each of the application's claims. The '617 patent issued on July 11, 1978.

On December 1, 1978, Seattle Box filed an application to have the '617 patent reissued with broader claims. Nist averred in support of this application that neither the

patent examiner nor the cited prior art required the narrow scope of the issued claims, and that the limitation on the height of the spacer block in his Claim 1 was unnecessary and "arose through inadvertence by counsel." Nist additionally stated that "in reality each overlying or superposed sleeper need only be separated from its underlying companion a distance equal to but not less than the diameter (*i.e.*, the thickness) of the pipes in each tier interposed between the sleepers to avoid forces being applied to squeeze the pipe in bundle stacks or handling operations * * *."

The PTO granted the application for the reissue patent and issued the '373 reissue patent on August 19, 1980. In addition to allowing Seattle Box to amend Claim 1 to specify a spacer block "of a height *substantially equal to or* greater than the thickness of the tier of pipe length" [emphasis in original], the PTO also allowed five wholly new claims, Claims 8–12.

The reissued, amended Claim 1, upon which claims 2–6 depend, is a product claim for:

1. A shipping bundle formed of a plurality of lengths of pipe of a common size, comprising:

a base formed of a first plurality of transverse sleepers located in spaced-apart parallel arrangement;

a tier of pipe lengths resting on said base, adjacent pipe lengths of said tier being separated by blocks in transverse series, each block having opposed concavities substantially embracing the curved sides of said adjacent pipe lengths;

each of said series of blocks being located to stand on one of said sleepers and being of a height *substantially equal to or* greater than the thickness of the tier of pipe lengths;

a second plurality of sleepers, each traversing said pipe tier in overlying alignment with a sleeper of said first plurality, the sleepers of said second plurality being supported on the series of separating blocks; and

a bundling strap tightly encircling each sleeper of said first plurality, the separating blocks resting thereon, and the respective overlying sleeper. [Emphasis in the claim.]

The reissued, new Claim 8, upon which claims 10 through 12 depend, is a claim for a process using:

8. The method of bundling a plurality of lengths of pipe of a common size, comprising:

forming a first bundle base by laying down a first plurality of transverse sleepers in spaced-apart parallel locations;

depositing a first tier of pipes on said bundle base and at each location concavely chocking adjacent pairs of pipes of said tier in spaced-apart relation;

traversing the first tier of pipes with a second plurality of transverse sleepers aligned with said first plurality at each location and vertially [sic] spaced apart by said chocking from said first plurality a distance substantially equal to or greater than the diameter of said pipes;

tightly encircling the pipes of said first tier with strapping adjacent at least two of said locations; and,

tightly encircling the sleepers at each location with strapping.

Claims 7 and 9, withdrawn before trial, are not at issue here.

II

Issues

The parties argue three main issues in this appeal:

1. Did the trial court err in not holding the Nist '373 reissue patent invalid (a) for obviousness under 35 U.S.C. § 103, (b) for indefiniteness under 35 U.S.C. § 112, or (c) under the recapture rule for obtaining through reissue claims of improper scope?

2. Did the trial court err in (a) finding that Industrial presently infringes claims of the '373 reissue patent and (b) enjoining that infringement?

3. Did the trial court err in (a) finding that Industrial infringed claims of the '617 patent before the '373 reissue patent issued and (b) holding Industrial liable for that infringement?

III

Validity

A. *Section 103—"Obviousness"*

[1, 2] We are, once again, confronted with a challenge to a trial court's judgment on the issue of obviousness. We begin, as usual, with a careful review of the district court's fact-findings made according to the Supreme Court's prescribed ritual: "the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved." *Graham v. John Deere Co.*, 383 U.S. 1, 17, 86 S.Ct. 684, 693, 15 L.Ed.2d 545, 148 USPQ 459, 467 (1966). We cannot and will not set these fact-findings aside unless the appellant persuades us that the findings are *clearly* erroneous. *Fed.R.Civ.P.* 52(a). Since Industrial has not left us here with a definite and firm conviction that the trial judge has committed a mistake, we rely fully on the district court's findings.

1. *Factual Determinations*

a. *Scope and Content of the Prior Art*

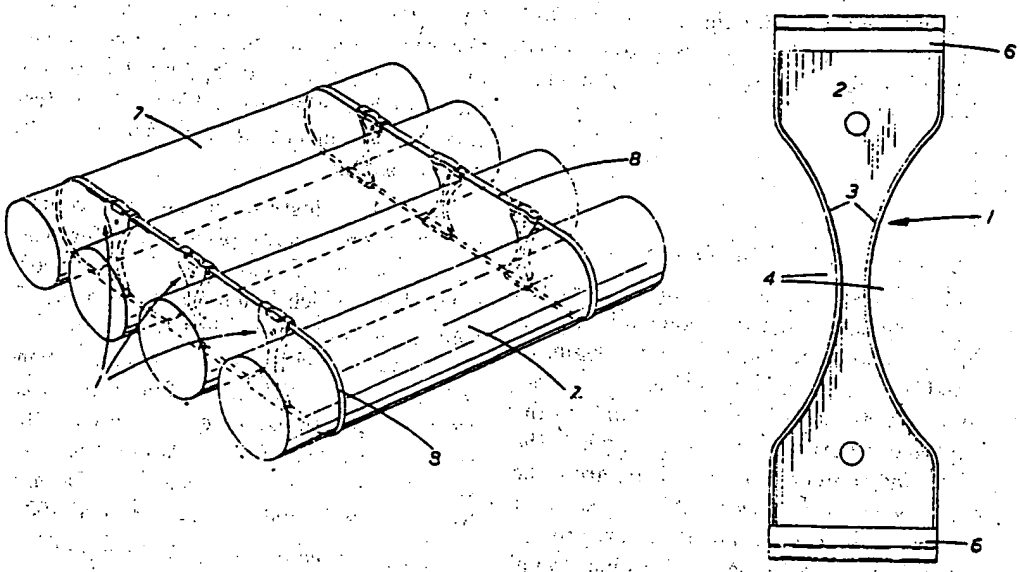
Before trial, Industrial identified as prior art some seventy United States patents, three West German patents, a 1960 Association of American Railroads ("AAR") publication entitled "Rules Governing the Loading of Steel Products Including Pipe on Open Top Cars," and a United States Government leaflet on storage and materials handling. It is undisputed that no single prior art reference exhibits all the features of the invention claimed in the '373 reissue patent.

At trial, Industrial focused the court's attention on several prior art references which the patent examiner had not considered and which Industrial deemed significantly more pertinent than those references the examiner did cite. Industrial concentrated, in particular, on four references which the patent examiner did not cite: the AAR publication; British Patent No. 561,423, issued 1944; and Parker U.S. Patents Nos. 1,801,451, and 1,821,234, issued 1931.

The district court expressly held that this art was not more pertinent than the art which the patent examiner cited. The parties here have completely fashioned their argument around this art, however. We assume, therefore, that this art is appropriate for purposes of reviewing the district court's holding of nonobviousness.

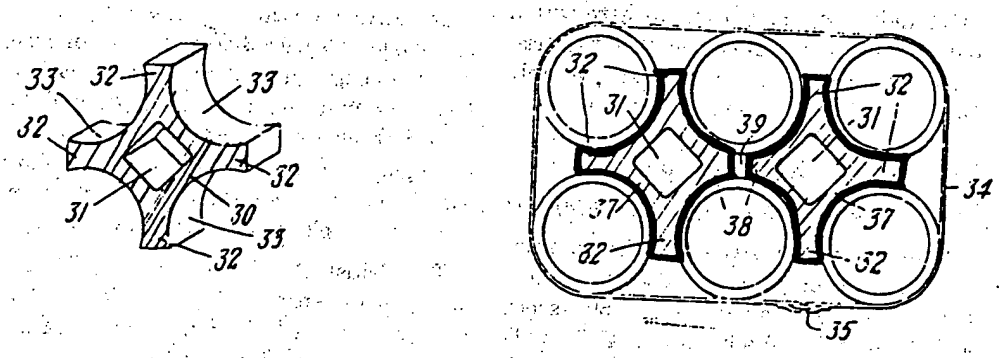
The AAR publication discloses the use of (1) wooden sleepers between rows of pipe, (2) strapping material passing at various levels around the tiers of pipe, and (3) "wood chock blocks" cut to fit the contour of the pipe. The wood blocks, however, are *nailed* to only the *ends* of the sleepers; they are not placed between individual pipe.

The British Patent No. 561,423 discloses sheet metal spacers formed with double-concave faces which match the curvature of bundled cylindrical articles.

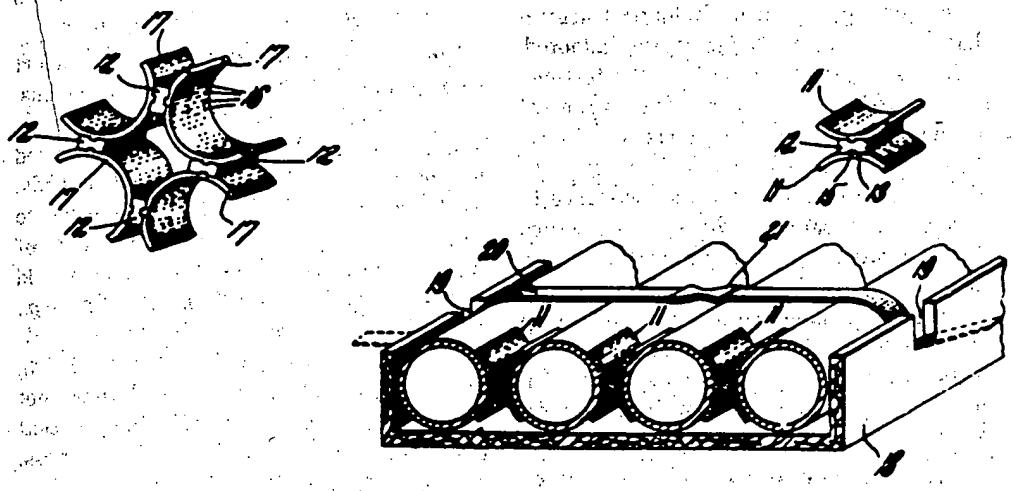


British Patent No. 561,423

Parker Patents Nos. 1,821,234 and 1,801,451 disclose spacers having double-concave sides to hold conduits in a spaced relationship. The Parker patents also disclose spacers used to support two tiers of pipe.



Parker Patent No. 1,801,451



Parker Patent No. 1,821,234

b. *Differences Between Prior Art and '373 Reissue Claims.*

The trial court found that although most of the elements of Nist's invention were known, nothing in the prior art disclosed a double-concave block adapted to provide vertical support for a layer or more of pipe located on sleepers above a bottom layer of pipe. The prior art, that is, nowhere taught using wooden spacer blocks with a weight bearing capacity to support sleepers.

c. *Level of Skill*

The district court found "the level of skill in the pipe packaging art at the time Nist made this invention to be that * * * [of] persons familiar with the packaging of tubular goods for safe transportation from a packaging site to a remote location, with such persons having engineering or mechanical skills acquired by actual experience."

d. *Other Considerations*

The district court made several additional fact-findings which are relevant when reviewing an invention's obviousness. The court noted, in particular, that Nist solved after extensive experimentation a long-felt but unsolved need for an improved pipe bundle, and that Seattle Box enjoyed commercial success with its claimed bundle.

2. *Legal Determinations*

[3, 4] The district court held that Industrial did not meet its burden of overcoming the '373 patent's statutory presumption of validity, 35 U.S.C. § 282. Industrial simply reargues to us its position that the facts clearly show the obviousness of the invention, relying on the "pertinence" of its newly discovered prior art. Industrial makes two fundamental errors, however. First, Industrial seems to forget that the district court expressly held that Industrial's art was *not* more pertinent than the art which the patent examiner cited. This court does not consider evidence *de novo*. *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, at 1543 (Fed.Cir. 1984). Second, even if the art were more pertinent, this fact alone does not rebut the statutory presumption of validity. *Leinoff v. Louis Milona & Sons, Inc.*, 726 F.2d 734, 738, 220 USPQ 845, 847–48 (Fed.Cir.1984).

In denouncing the district court's adverse holding, however, Industrial argues that the district court improperly adopted, and thus incorrectly relied on, the testimony of Seattle Box's expert. This argument has no merit. A trial judge has sole discretion to decide whether or not he needs, or even just desires, an expert's assistance to understand a patent. We will not disturb that discretionary decision except in the clearest case. This is not such a case. Here, the trial judge reasonably could have believed he needed the testimony of experts to aid him with the sometimes complex patent specifications and prior art references.

Industrial bore the burden in trial of persuasion that one of ordinary skill in the art *would have found* the subject matter claimed, *as a whole*, obvious *at the time* the invention was made. Industrial did not meet this burden; the facts do not clearly show it did. The invention comprises some features found in the prior art and some that are new and, in our view, not even suggested by the prior art. *In re Sernaker*, 702 F.2d 989, 217 USPQ 1 (Fed.Cir. 1983). The prior art did not suggest the combination of features made here. We affirm the district court's analysis of and holding on Industrial's section 103 defense.

B. *Section 112—"Indefiniteness"*

[5] Industrial argues that the use of the term "substantially equal to" in the '373 patent's claims makes the claimed subject matter indefinite and the claims invalid under 35 U.S.C. § 112. Industrial contends, it appears, that since its patent counsel was uncertain as to just how equal "substantially equal to" is, the claims must be indefinite.

Definiteness problems often arise when words of degree are used in a claim. That some claim language may not be precise, however, does not automatically render a claim invalid. When a word of degree is used the district court must determine whether the patent's specification provides some standard for measuring that degree. The trial court must decide, that is, whether one of ordinary skill in the art would understand what is claimed when the claim is read in light of the specification.

The trial court found here that an expert would know the limitations of the claims. The specification clearly sets forth, for example, that the divider blocks are intended to absorb the weight of overhead loads. Furthermore, even if Industrial needed to experiment so as to determine the limits of the '373 patent's claims, the claims would not be invalid under section 112. *See, e.g., W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1557, 220 USPQ 303, 316 (Fed.Cir.1983). Industrial has not carried its burden of persuading us that the '373 patent is invalid for indefiniteness.

C. *Recapture Rule*

[6] Industrial argues that the PTO incorrectly allowed the broadened reissue claims with a scope equivalent to the scope of the preamended claims in the original patent application. The recapture rule does not apply here, however, because there is no evidence that Seattle Box's amendment of its originally filed claims was in any sense an admission that the scope of that claim was not in fact patentable. *See In re Petrow*, 402 F.2d 485, 488, 159 USPQ 449, 451 (CCPA 1968); *see also Ball Corp. v. United States*, 729 F.2d 1429 (Fed.Cir.1984).

IV

Liability

The court must consider Industrial's liability for infringement, if any, during two distinct time frames. The first period extends between the date the original patent issued, July 11, 1978, and the date the reissue patent issued, August 19, 1980. Seattle Box's only enforceable patent rights during this period arise from 35 U.S.C. § 252, which allows claims in a reissue patent to reach back under certain circumstances to the date the original patent issued. The second period begins on the date the reissued patent issued, August 19, 1980. During this period, Seattle Box's broadened patent claims cover a double-concave block with a height "substantially

equal to or greater than" the diameter of the separated pipes. We consider the two time periods *seriatim.*

A. *Activities Occurring Before the '373 Reissue Patent Issued.*

Industrial asserts that the district court erred in finding it liable for infringement done before the '373 reissue patent issued. We agree.

[7] An original patent cannot be infringed once a reissue patent has issued, for the original patent is surrendered. At one point in the history of the American patent law, this surrender precluded any action for infringement for acts done prior to the surrender. Courts would not allow a patentee to *bring* an action in response to acts done before the reissue patent issued since no patent existed upon which one could allege infringement. Courts, moreover, would dismiss for a failure to state a cause of action any action *filed* before the patent was surrendered since the patent sued on no longer existed. Courts acted, in other words, as if the original patent never was. *See* Federico, *Intervening Rights in Patent Reissues,* 30 *Geo.Wash.L.Rev.* 603, 605 (1962).

To ameliorate the harsh effect of a patent's surrender, Congress has legislated that under certain circumstances claims of the original patent have a form of continuity if carried over to the reissue patent. Congress has incorporated its most recent version of this rule into 35 U.S.C. § 252, the first paragraph of which provides that:

> The surrender of the original patent shall take effect upon the issue of the reissued patent, and every reissued patent shall have the same effect and operation in law, on the trial of actions for causes thereafter arising, as if the same had been originally granted in amended form, but *in so far as the claims of the original and reissued patents are identical,* such surrender shall not affect any action then pending nor abate any cause of action then existing, and the reissued patent, *to the extent that its claims are identical with the original patent,* shall constitute a continuation thereof and have effect continuously from the date of the original patent. [Emphasis supplied.]

Congress, in this statute, has explicitly limited claim continuity to claims in the reissued patent *identical* to claims in the original patent. The statute does not allow the claims of the original patent some other form of survival. The original claims are dead. The statute permits, however, the claims of the reissue patent to reach back to the date the original patent issued, *but only if* those claims are identical with claims in the original patent. With respect to new or amended claims, an infringer's liability commences only from the date the reissue patent is issued.

At issue in this case is Congress' meaning of the word "identical." The district court interpreted "identical" to mean "essentially identical," noting that other courts have interpreted the word "identical" in section 252 in a way which does not limit claim continuity to literally identical claims. It cited *Austin v. Marco Dental Products, Inc.,* 560 F.2d 966, 195 USPQ 529 (9th Cir.1977), *cert. denied,* 435 U.S. 918, 98 S.Ct. 1477, 55 L.Ed.2d 511 (1978) and *Akron Brass Co. v. Elkhart Brass Manufacturing Co.,* 353 F.2d 704, 147 USPQ 301 (7th Cir.1965).

Akron Brass and *Austin* permitted changes in a reissue patent's claims, however, only if *without substance.* In *Akron Brass,* a reissued claim substituted the word "outlet" for the word "inlet" in the original claim. Since it was already clear what was intended, the court there noted, substitution of "outlet" for "inlet" in no way enlarged or modified the substance of the claim. In *Austin,* the court found a claim in the reissued patent "identical" to one in the original patent where a modification was made to "make more precise the language used without substantive changes in the claims." 560 F.2d at 973, 195 USPQ at 534.

[8] Since we are not asked to, we do not have to decide exactly what "identical" does mean. It is clear, though, that "iden-

tical" means, *at most*, "without substantive change." Seattle Box, in broadening its claims' scope to cover not only spacer blocks "greater than" but also "substantially equal to" the diameter of the pipes in a bundle, has, in our view, made substantive change to its claims. The original claims cannot reasonably be read as intending, but for some inaccuracy in their expression, the same coverage as the reissue claims. Here, the addition is not a matter of a mere clarification of language to make specific what was always implicit or inherent.

We hold, therefore, that Seattle Box's broadened reissue claims, with the added words "substantially equal to," are not "identical" to its original claims, assuming "identical" means "without substantive change." The district court erred in interpreting "identical" in section 252 to mean "essentially identical." Thus, Seattle Box cannot collect damages for any activities performed before its new and broadened claims issued in the reissue patent. We reverse the trial court's award of damages against Industrial for acts done prior to the date the reissue patent issued.

B. *Activities Occurring After the '373 Reissue Patent Issued.*

Industrial argues that since Seattle Box gave up its claim to spacer blocks "substantially equal to" the diameter of the separated pipe during prosecution of the '617 patent, the doctrine of file wrapper estoppel prevents Seattle Box from "recapturing" that language under the doctrine of equivalents. Industrial contends, furthermore, that even if we affirm the district court's finding of infringement under the doctrine of equivalents, the doctrine of intervening rights, 35 U.S.C. § 252, saves Industrial from liability. We consider the infringement argument first.

1. *Infringement*

[9] The trial court found that Industrial's pipe bundles "clearly included each of the elements of claims 1 through 5, 8, 10 and 11 of Re. 30,373." Industrial admits that its bundles utilize the general elements of the claims in issue, namely, sleepers, pipes, double-concave spacer blocks, and strapping material. In dispute is the scope of Seattle Box's reissued claim 1 which requires as a necessary element of the invention a spacer block "being located to stand on one of said sleepers and being of a height *substantially equal to or* greater than the thickness of the tier of pipe lengths." [Emphasis in original.]

Industrial asks us to decide whether the '373 reissue patent's claims can have the effect of covering spacer blocks which are "slightly shorter" than the diameter of oil pipes which they separate. Industrial argues, first, that since Seattle Box gave up the phrase "substantially equal to" during its prosecution of the original patent application, it cannot assert that scope here. Industrial appears throughout its argument to forget that Seattle Box does not allege in this action infringement of its original claims, but rather, alleges infringement of presumably valid *reissue* claims. These claims *specifically* extend to spacer blocks "substantially equal to" the separated pipes' diameters. Seattle Box has every right to assert the full scope of its claims here.

Industrial next argues that its spacer blocks are not substantially equal to the diameter of the separated pipes, as the claims require. Industrial contends that on the advice of its patent counsel, and specifically to avoid infringement, it instructed its spacer block manufacturer to make the spacer blocks for 5½" pipes at least one-sixteenth of an inch *less than* the pipe diameter.

[10] The district court found that the "slightly shorter, double-concave Industrial blocks would correspond to the 'substantially equal to' limitation * * *" under the doctrine of equivalents. The court's belief that it found infringement under the doctrine of equivalents, however, is wrong. The doctrine of equivalents only comes into play when there is no literal infringement. *See Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1361, 219 USPQ 473, 480

(Fed.Cir.1983). Since "substantially equal to" embraces "slightly less than," the district court's finding that Industrial's "slightly shorter" spacer blocks *were* "substantially equal to" the pipe diameter is a finding of literal infringement which is not clearly erroneous.

The district court expressly found infringement, though, only in regard to spacer blocks one-sixteenth of an inch less than the diameter of the separated pipe. This finding we affirm. The report of the Special Master concerning Seattle Box's lost profits, however, indicated that after trial had ended, Industrial made 84 pipe bundles with spacer blocks *one-quarter* of an inch less than the diameter of the separated pipe. The Special Master correctly refused to consider whether *these* blocks infringed the '373 reissue patent; he simply detailed the profits lost due to these bundles. The district court awarded damages for these bundles without making any express finding as to whether they infringed the '373 patent.

As we indicated earlier, the trier of fact must determine the scope of an imprecise phrase such as "substantially equal to," which, by its very nature, has a fact-dependent meaning. The fact that a spacer block one-sixteenth of an inch less than a pipe diameter infringes a claim does not necessarily indicate that a spacer block one-quarter of an inch less than a pipe diameter also infringes that claim. There is a new literal infringement issue to decide: are spacer blocks one-quarter of an inch less than the diameter of the separated pipe "substantially equal to" the diameter of those separated pipes? The trier of fact must make express findings in response to this question. Such findings help delineate the metes and bounds of the claim, and enable the alleged infringer to determine what it must do to avoid infringement. We therefore vacate the award of damages as to the 84 bundles using spacer blocks one-quarter of an inch less than the diameter of the separated blocks and remand for the necessary findings of fact.

[11] We limit the remand in this case, however, to a determination of whether the quarter-inch short spacer blocks literally infringe the claims in issue. Normally, if the trier of fact has found that there is no literal infringement, it may consider whether there is infringement under the doctrine of equivalents. Here, however, Seattle Box expressly stated during prosecution of its reissue patent that a sleeper "need only be separated from its underlying companion a distance equal to *but not less than* the diameter (*i.e.*, the thickness) of the pipes in each tier interposed between the sleepers." [Emphasis supplied.] Since the claims issued for a separation "substantially equal to" the pipes' diameter, we recognize that some leeway is appropriate in determining literal infringement. Where no literal infringement exists, however, Seattle Box's statement during its prosecution of the reissue patent estops it from asserting that its claims have a broad effect under the doctrine of equivalents.

2. *Section 252—Intervening Rights*

[12, 13] When a reissue patent issues, a new patent with presumably valid claims exists. The reissue patent has "the same effect and operation in law, on the trial of actions for causes *thereafter arising*, as if the same had been originally granted in amended form, * * *" 35 U.S.C. § 252 [emphasis supplied].

The language quoted above expressly prevents a court from giving any consideration to the protection of intervening rights. The second paragraph of section 252 modifies the first paragraph, however, so as to protect intervening rights. The second paragraph provides, in pertinent part:

> No reissued patent shall abridge or affect the right of any person * * * who made * * * or used prior to the grant of a reissue anything patented by the reissued patent, to continue the use of * * * the specific thing so made * * * or used, unless the making [or] using * * * of such thing infringes a valid claim of the

reissued patent which was in the original patent * * *.

The statute sets forth a single straightforward test for determining whether the doctrine of intervening rights protects an alleged infringer. The only question to ask under this test is whether claims of the original patent which are repeated in the reissue patent are infringed. Section 252 assumes that a patentee having valid claims in a patent will retain those claims in the reissued patent. If valid claims in the original patent appear unaltered in the reissue patent, the doctrine of intervening rights affords no protection to the alleged infringer.

[14] We have already held, however, that the claims appearing in Seattle Box's reissued patent are substantively different than those in the original patent. That is, Seattle Box repeats *no* claim from its original patent in its reissued patent. Industrial, therefore, may properly raise a defense of intervening rights. *See Cohen v. United States*, 487 F.2d 525, 203 Ct.Cl. 57, 179 USPQ 859 (1973).

[15] When the doctrine of intervening rights is properly raised, the court must consider whether to use its broad equity powers to fashion an appropriate remedy. The second paragraph of section 252 states:

> [The court] may provide for the continued manufacture, use or sale of the thing made * * * or used as specified, or for the manufacture, use or sale of which substantial preparation was made before the grant of the reissue, and it may also provide for the continued practice of any process patented by the reissue, practiced * * * prior to the grant of the reissue, to the extent and under such terms as the court deems equitable for the protection of investments made or business commenced before the grant of the reissue.

The court is given the discretion to fashion a remedy from a wide range of options available to it. The court may, for example, (1) confine Industrial to the use of those double-concave blocks already in existence, (2) permit Industrial to continue in business under conditions which limit the amount, type, or geographical location of its activities, or (3) permit Industrial to continue in business unconditionally.

The trial court, properly to exercise its equity powers, must carefully weigh standard equitable considerations. Since the trial court incorrectly held section 252 inapplicable here, it has yet to make any findings as to the equities of this case. Accordingly, we vacate this portion of the district court's judgment and remand the case for further proceedings consistent with this opinion.

V

Conclusion

We affirm the district court's holding that the '373 reissue patent is valid. We affirm its finding that some of Industrial's spacer blocks infringe the patent, but vacate the finding of infringement as to other blocks. We reverse the district court's finding of liability for any activities Industrial performed *before* the '373 reissue patent issued. Finally, we vacate the district court's conclusions as to the scope of relief to which Seattle Box is entitled for infringement *after* the '373 reissue patent issued. We remand this case to the district court for further proceedings. Each party to bear its own costs.

AFFIRMED IN PART, REVERSED IN PART, VACATED IN PART, AND REMANDED.

APPENDIX 14

Summary of Prior Art and Other Relevant Rejections; and Arguments in Reply to Rejection of Claims of Interest to this Appeal

Appendix 14

Summary of Prior Art and Other Relevant Rejections; and Arguments in Reply to Rejection of Claims of Interest to this Appeal

Rejection No. & Date	Serial No. & Filing Date	Statutory Basis	Summary of Rejection	Summary of Responsive Claim Amendment & Date
1 7/20/88	'520 12/16/87	§112, ¶2	Claims 1-6 rejected as improper Markush group.	Amendment "A" on 1/23/89 (PTO Stamp Date) replaced "comprising" with – consisting of – in claim 1.
2 7/20/88	'520 12/16/87	§102 (b), (e)	Claims 1-16 rejected as anticipated by Cairns and Dicker on treatment of asthma, colitis and reversible obstructive airways disease	In the 1/23/89 Amendment "A", this anticipation rejection was traversed by a showing of limitations in the rejected claims not found in single prior art reference.
3 7/20/88	'520 12/16/87	§102 (b)	Claims 1-16 rejected as anticipated by Cox on treatment of reversible obstructive airways disease	In the 1/23/89 amendment, this anticipation rejection was traversed by a showing of limitations in the rejected claims not found in the prior art reference.
4 7/20/88	'520 12/16/87	§ 103	Claims 1-16 rejected as obvious in view of Cox	In the 1/23/89 Amendment "A" a declaration showing unexpected advantages was submitted.
5 4/3/89	'520 04/03/89	§102 (b), (e)	Claims 1-17 rejected as anticipated by or obvious from Cairns and Dicker on ground that	Response "B" of 6/21/99 was submitted, but not entered into the application. The Response argued that all claims require (1)

Rejection No. & Date	Serial No. & Filing Date	Statutory Basis	Summary of Rejection	Summary of Responsive Claim Amendment & Date
			each anticipates treatment of asthma, colitis and reversible obstructive airways disease	aqueous solution and (2) specific active ingredient, and that no single reference (Cairns, Dicker or Cox) discloses both.
6 4/3/89	'520 04/03/89	§103	Claims 1-17 rejected as obvious over Cairns and Dicker on ground that they render treatment of asthma, colitis and reversible obstructive airways disease obvious	Response "B" of 6/29/89 includes declaration of unexpected results. Response "B" not entered into the application.
7 4/3/89	'520 04/03/89	§102 (b)	Claims 1-17 rejected as anticipated by Cox anticipates on the ground that he discloses treatment of reversible obstructive airways disease	Response "B" of 6/29/89 submitted, but not entered into the application. Response argued that all claims require (1) aqueous solution and (2) specific active ingredient, and that no single reference (Cairns, Dicker or Cox) discloses both.
8 4/3/89	'520 04/03/89	§103	Claims 1-17 rejected as obvious from Cox on the ground that Cox renders obvious the treatment of reversible obstructive airways disease	Response "B" of 6/29/89 includes declaration of unexpected results submitted. Response "B" not entered into the application.
9 3/8/90	'020 09/20/89	§102 (b), (e)	Claims 1-14 and 17 rejected as anticipated by Cairns and Dicker on ground of treatment of asthma, colitis and	Amendment "A" of 9/12/90 (PTO Mail Room receipt date) further amends claim 1 to delete the eye, nasal and colon diseases aspect of the claims and

Rejection No. & Date	Serial No. & Filing Date	Statutory Basis	Summary of Rejection	Summary of Responsive Claim Amendment & Date
			reversible obstructive airways afflictions.	to limit the administration to the disodium salt of the active ingredient. Amendment made to more clearly focus the patentability issues related to the rejection and treatment of reversible obstructive airways disease. Other claims, not relevant to the present appeal also were amended. None of Cairns, Dicker or Cox discloses use of aqueous solutions of nedocromil sodium for treatment of any disease.
10 3/8/90	'020 09/20/89	§103	Claims 1-14 and 17 rejected as obvious over Cairns and Dicker on ground to teaching of treatment of asthma, colitis and reversible obstructive airways disease obvious	See above. Plus, any *prima facie* obviousness is overcome by declarations establishing unexpected results.
11 3/8/90	'020 03/08/90	§102 (b)	Claims 1-17 rejected as anticipated by Cox.	See above summary re § 102(b)(e) rejections,
12 3/8/90	'020 09/20/89	§103	Cox renders obvious the treatment of reversible obstructive airways disease	See above summary re § 103 rejection.
13 3/8/90	'020 09/20/89	§103	Claims 1-17 rejected as obvious over Fisons Japanese	Original claim 1 is amended, as stated above. Fisons '722 limited to treatment of

Rejection No. & Date	Serial No. & Filing Date	Statutory Basis	Summary of Rejection	Summary of Responsive Claim Amendment & Date
			publication '722 on the ground that the publication teaches the claimed compound in an eye treatment and appears to anticipate the present claims.	eye diseases associated with diabetes and thus would not suggest the method now claimed to one skilled in the art.
14 12/10/90	'020 9/20/89	§102 (b), (e)	Claims 1, 7, 9-12 and 17 rejected as anticipated by Cairns and Dicker on ground of treatment of asthma, colitis and reversible obstructive airways disease	Proposed Amendment "B" of 6/12/91 (PTO Mail Room receipt date) cancels original claim 1 and replaces it with new proposed first claim 18. Proposed amendment is not entered into the application. [Proposed first claim 18 reintroduces the 6 types of eye diseases, the 3 types of nasal diseases, the reversible obstructive airways disease and the 3 types of colon diseases. Proposed first claim 18 also limits administration to soft, carbon dioxide permeable, plastics ampoule, sterile filled with unit dose of aqueous solution of active ingredient having pH 3.5 to 6.0. None of Carins, Dicker, Cox or Fisons '722 has "soft plastic ampoule."] Argument now shifts to patentability based on the soft plastic ampoule. Proposed Rule 116 Amendment "B" not

Rejection No. & Date	Serial No. & Filing Date	Statutory Basis	Summary of Rejection	Summary of Responsive Claim Amendment & Date
				entered.
15 12/10/90	'020 9/20/89	§103	Claims 1, 7, 9-12 and 15-17 rejected as obvious over Cairns and Dicker re treatment of asthma, colitis and reversible obstructive airways disease obvious	See above.
16 12/10/90	'020 9/20/89	§102 (b)	Claims 1, 7, 9-12 and 15-17 rejected as anticipated by Cox on ground of treatment of reversible obstructive airways disease	See above.
17 12/10/90	'020 9/20/89	§103	Claims 1, 7, 9-12 and 15-17 rejected as obvious under Cox disclosure of treatment of reversible obstructive airways disease	See above.
18 12/10/90	'020 9/20/89	§103	Composition claims 7, 9-12 and 17 rejected under § 102 or § 103 as unpatentable over Fisons '722	Not applicable to the recapture estoppel issue on appeal here because these claims are not directed to a method of treatment of eye disease. Rather, they are directed to composition claims.
19 12/10/90	'020 9/20/89	§103	Composition claims 7, 9-12 and 17 are rejected under 35 U.S.C. § 103 as unpatentable over Auty, Corrado, Neale or Schwaltz	Not applicable because the claims are composition claims; not method claims as on appeal.

Rejection No. & Date	Serial No. & Filing Date	Statutory Basis	Summary of Rejection	Summary of Responsive Claim Amendment & Date
20 12/10/90	'020 9/20/89	§103	Claims 1, 7, 9-12 and 15-17 rejected as obvious over Cox, Cairns or Dicker in view of Cairns '85 publication or Auty render treatment of reversible obstructive airways disease	See above.
Note: Two claim 18's were submitted; only the second claim 18 was entered into the application.				Preliminary amendment in Serial No. '574 filed 8/7/91 (Patent Office Mail Room receipt date) includes second proposed claim 18, which differs from first proposed claim 18 in that it recites the contents of a "container" rather than a "soft ampoule;" as in the Proposed Amendment "B" of the parent does not recite it to be "sterile-filled" and includes the acid and pharmaceutically acceptable salt forms of the active ingredient.
21 4/8/92	'574 8/7/91	§112, ¶2	Claims 7, 10 and 17-22 are rejected on ground that the term "container" is indefinite, and the term "sterile-filled" is indefinite.	In an amendment dated 10/13/92 (PTO Date Stamp), claim 18 was amended to substitute --ampoule— for "container"
22 4/8/92	'574 8/7/91	§103	Claims 7, 10 and 17-22 were rejected as obvious over Brown in view of Cox & GB # 291,	In an Amendment "A" dated 10/13/92 (PTO Mail Room receipt date) argument was presented that (1) GB #291 is

Rejection No. & Date	Serial No. & Filing Date	Statutory Basis	Summary of Rejection	Summary of Responsive Claim Amendment & Date
			on the ground that Brown teaches nedocromil sodium for inhalation; Brown teaches Crohn's & reversible airway obstructions; GB # 291 teaches reversible obstructive disease; and Cox teaches reversible obstructive airways disease, and hard/soft capsules.	equivalent to Brown; (2) Brown has pH of 5.0 to 7.5; (3) Brown does not teach an aqueous solution; rather he discloses a process of making solid nedocromil sodium that is not even a pharmaceutical; (4) Examiner got concentration wrong: 33% - 17%; not 0.1-5; (5) Cox does not teach nedocromil; rather he teaches pyranoquinoline (closely related, but different compound) and thus Cox teaches away; (6) Cox teaches soft capsules to be swallowed; not plastic ampoule as claimed.
23 11/10/92	'574 8/7/91	§103	Final rejection of claims 7, 10 and 17-22 as obvious under Brown in view of Cox and GB # 291 Brown not equivalent to GB # 291; GB #291 has the claimed pH range of 3.5 to 6.0. Treats reversible obstructive conditions of the airway. Cox directed to Crohn's and reversible airway obstruction	In a proposed Amendment "B" After Final Rejection dated 5/12/93 (Patent Office Mail Room receipt date), it was proposed that in claim 18, line 10 after "aqueous," – pharmaceutical—was to be inserted. Arguments were made to the effect that the Examiner was wrong re Brown; both references teach pH 5.0-7.5; not 3.5 top 6.0. Brown has aerosol propellant; not aqueous solution. More argument re capsule, aqueous solution and what is/is not pharmaceutical. This

Rejection No. & Date	Serial No. & Filing Date	Statutory Basis	Summary of Rejection	Summary of Responsive Claim Amendment & Date
				amendment was not entered into the '574 application; but was entered as a preliminary amendment in the next application (the '804 application, below).
	'804 6/25/93			The proposed Amendment "B" from the parent '574 application was entered as a preliminary amendment in the '804 application.
24 1/5/94	'804 6/25/93	§103	Claims 7, 10 and 17-22 were rejected as obvious over Brown v Cox & GB #291. Cox teaches active ingredient and method of treatment of reversible obstructive airways disease (18:64-65) and Crohn's disease (19:59).	In a Response "A" dated July 5, 1994 (Applicants' mailing date) no amendment to any claim was made. Rather, more argument was presented, with a good summary of issues and teachings of references.
25 10/19/94	'804 10/19/94	§103	Final rejection of claims 7, 10 and 17-22 as obvious over Brown v Cox & GB #291. Examiner alleges that Cox teaches active ingredient and method of treatment of reversible obstructive airways disease (18:64-65) and Crohn's disease (19:59). GB #291 pH reads	In an Amendment "B" After Final dated February 6, 1995 (Patent Office Mail Room receipt date), claims 7, 10, 17-22 are cancelled. New claims 23-25 are added. Broadest method claim is new method claim 23, directed to method of treating a reversible obstructive airways disease comprising . ... Amendment made "to present the rejected

Rejection No. & Date	Serial No. & Filing Date	Statutory Basis	Summary of Rejection	Summary of Responsive Claim Amendment & Date
			on claim [Note: examiner states test backwards when it is stated that all art "reads on composition for treatment of reversible obstructive condition of the airways" and Crohn's].	claim in a better form for allowance or appeal. Applicants stated that they continued to believe that amendments and reasoning set forth on 7/11/94 amendment were sufficient to overcome the rejection under §103.

APPENDIX 15

Fisons '722 Prior Art Publication

PTO 90-2175

Japanese Kokai Patent No.
Sho 58[1983]-4722

PHARMACOLOGICAL METHOD

Philip Seard

UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. APRIL 26, 2990

Code: PTO 90-2175

JAPANESE PATENT OFFICE

PATENT JOURNAL

KOKAI PATENT NO. SHO 58[1983]-4722

Int. Cl.^{3}:	A 61 K 31/35 31/38 31/47
Sequence Nos. for Office Use:	6408-4C 6408-4C 6675-4C
Application No.:	Sho 57[1982]-107709
Application Date:	June 24, 1982
Publication Date:	January 11, 1983
Priorities Claimed:	(32) June 25, 1981, (33) Great Britai (GB), (31) 8119624
No. of Inventions:	1 (Total of 7 pages)
Examination Request:	Not requested

PHARMACOLOGICAL METHOD
[Yakugakuteki hoho]

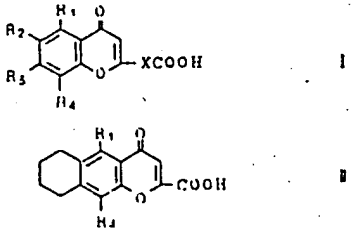
Inventors: Philip Seard

Applicant: P.L.C. Fisons

[There are no amendments to this patent.]

Claims

1. Method of administering the following agents to patients suffering or likely to suffer from cataracts, diseases of the retina, nervous system, blood vessels, and kidneys related to diabetes mellitus or galactosemia in the sense of prevention therapy:
6-methylamino-4-oxo-10-propyl-4H-pyrano[3,2-g]quinoline-2,8-dicarboxylic acid, 1-ethyl-4,6-dioxo-10-propyl-4H, 6H-pyrano[3,2-g]quinoline-2,8-dicarboxylic acid or compounds represented by formulas I, II, or III,



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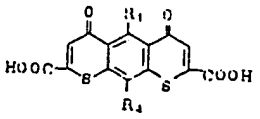


II

where R_1 indicates hydrogen or a hydroxyl, alkyl or hydroxyalkoxy group, R_2 and R_3 indicate the same or different alkyl groups or hydrogen, R_4 indicates hydrogen or an alkyl or mono- or dihydroxyalkyl group, the R_3 and R_4 groups could combine to form a $-(CH_2)_4-$ chain, and X could be a bond or phenyl group, and their pharmacologically acceptable derivatives.

2. The method described in Claim 1 in which the active component exhibits activity like that of sodium cromoglycate [transliteration].

3. The method described in Claim 1 or 2 in which the active component is administered orally or by inhalation.

4. The method described in any of Claims 1-3 in which the active component consists of:

4,6-dioxo-5,10-dimethyl-4H,6H-benzo[3,2-g]dithiopyran-2,8-dicarboxylic acid,

4-[5-(2-hydroxypropyloxy)-4-oxo-4H-1-benzopyran-2-yl]benzoic acid,

6,7,8,9-tertrahydro-4-oxo-10-(2-hydroxypropyl)-4H-naphtho[2,3-b]pyran-2-carboxylic acid,

6,7,8,9-tetrahydro-10-(2,3-dihydroxypropyl-1-yl)-4-oxo-4H-naphtho[2,3-b]pyran-2-carboxylic acid,

7,8,9,10-tetrahydro-5-hydroxy-4-oxo-6-propyl-4H-naptho[1,2-b]-pyran-2-carboxylic acid,

6-methylamino-4-oxo-10-propyl-4H-pyrano[3,2-g]quinoline-2,8-dicarboxylic acid,

1-ethyl-4,6-dioxo-10-propyl-4H,6H-pyrano[3,2-g]quinoline-2,8-dicarboxylic acid, or their pharmacologically acceptable salts.

5. The method described in any of Claims 1-4 in which the active component is administered at a dose of 0.1-4000 mg/day.

6. The method described in any of Claims 1-5 in which the active component is in the form of a sodium salt.

Detailed explanation of the invention

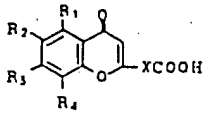
This invention is concerned with a new method of therapy. Although oral antidiabetic drugs such as sulfonylurea effectively reduce the blood glucose level, it has been clearly demonstrated that the chronic complications of diabetes, such as cataracts, and diseases of the nervous system, retina, blood vessels, and

kidneys, could not be prevented nor ameliorated by the use of such drugs. U.S. Patents Nos. 3,821,383, 4,117,230, 4,130,714, 4,127,665, and 4,210,667 suggested that various inhibitors of aldose-reducing enzymes were effective in this respect. Such compounds inhibit the enzymatic reduction of aldoses, such as glucose and galactose, to form the corresponding polyols such as sorbitol and galactitol, resulting in the prevention or reduction of the harmful and undesirable accumulation of polyols in the affected organs of the body. For example, the inhibition of glucose reduction prevents the accumulation of sorbitol, which is traumatic because of the osmotic pressure in the lens and the retina of the eye in diabetic cataracts, in the peripheral nerves in diabetic neuropathy, and in the kidneys in diabetic nephropathy.

It is well known that preventive antiallergic activity and bronchodilatory activity are shown in various monocromones, benzodipyrones, and flavones. However, we surprisingly discovered that these compounds could be used for the preventive as well as therapeutic treatment of cataracts, retinopathy, neuropathy, angiopathy, and nephropathy in patients with diabetes mellitus.

This invention offers a method to administer, to patients suffering or likely to suffer from cataracts, retinopathy, neuropathy, angiopathy, and nephropathy related to diabetes or galactosemia (abbreviated as "diseases"), in the sense of preventive as well as therapeutic treatment, the following compounds: 6-ethylamino-4-oxo-10-propyl-4H-pyrano[3,2-g]quinoline-2,8-dicarboxylic acid, 1-ethyl-4,6-dioxo-10-propyl-4H,6H-pyrano[3,2-g]quinoline-2,8-dicarboxylic acid, and compounds

represented by formulas I, II, and III as the active component, or their pharmacologically acceptable derivatives, preferably components with activity like that of sodium cromoglycate.



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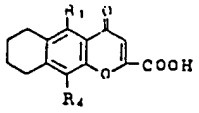

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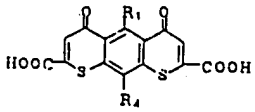

III

where R_1 indicates hydrogen or a hydroxy, alkyl, or hydroxyalkoxy group, R_2 and R_3 indicate the same or different group such as an alkyl group or hydrogen, R_4 indicates hydrogen or an alkyl or mono- or dihydroxy alkyl group, R_3 and R_4 could combine to form a $-(CH_2)_4-$ chain, and X indicates the absence of an atom or group or phenyl group [sic].

The compound with activity like that of sodium cromoglycate can inhibit the release of a pharmacological mediator from the combination of some types of antibodies and their specific antigens, for example, a reactive antibody and its specific antigen (British Patent No. 1,292,601 (Example 27) "Test of passive skin anaphylaxis").

The characteristics of compounds with activity like that of sodium cromoglycate are summarized by the results of the following biological tests.

A compound is tested in a passive anaphylaxis test in rats. The activity is evaluated as too low if no significant inhibition was induced in the development of an allergy by the intravenous (i.v.) or intraperitoneal (i.p.) injection of the compound at

20 mg/kg. In order to demonstrate that the antiallergic reaction is due to the inhibition of the release of an anaphylaxis mediator, rather than to peripheral tissue antagonist actions, anticholinergic activity, or stimulation of adenyl cyclase, various biological tests must be performed.

The pharmacologically acceptable derivatives of benzopyran-4-on-2-carboxylic acid and dithiopyrancarboxylic acid are pharmacologically acceptable salts, esters, and amides of the 2-carboxylic acid group.

As the proper salt, one can cite an ammonium salt, alkali metal salt (such as a sodium salt, potassium salt, and lithium salt), alkaline earth salt (such as a calcium salt or magnesium salt), and salts with the proper organic bases such as salts with hydroxylamine, methylamine, and ethylamine used as the lower alkylamines; salts with substituted lower alkylamines such as tri-(hydroxymethyl)-methylamine used as a hydroxy-substituted alkylamine; or salts of piperidine or morpholine used as single-ring nitrogen-containing heterocyclic compounds. As the proper esters, one can cite simple lower alkyl esters such as an ethyl ester; esters with alcohols containing a basic group, for example, 2-(diethylamino)-ethyl ester derived from a lower dialkylamino substituted alkanol; acyloxy lower alkyl esters such as piperoyl oxymethyl ester, or a bis-ester derived from a dihydric alcohol or substituted dihydric alcohol, such as bis-2-oxo-propane-1,3-di-yl ester. One can use an acid-added salt of a basic ester such as a hydrochloride salt, hydrobromide salt, oxalate salt, maleate salt, and fumarate salt. Esters can be produced by conventional methods such as esterification, ester exchange, or a reaction between an acid or its salt and the

proper compounds with removable groups. The amide can be a mono- or di-C_1-C_6 alkyl amide and can be produced by the conventional method of a reacting the ester of the corresponding acid with ammonia or a proper amine. It is preferable to use a sodium salt.

The method of this invention is used for the preventive as well as therapeutic treatment of the harmful enzymatic reduction of aldoses in the body, related to diabetes mellitus and galactosemia, with the chronic complications of cataracts, retinopathy, neuropathy, nephropathy, and angiopathy. The drug is administered to patients requiring treatment by oral administration, intravenous injection, intramuscular injection, subcutaneous injection, intraperitoneal injection, topical application, and application to the eyes (eye drops). Also, inhalation through the nose and mouth could be applied.

In the preparation of the proper product, the active component is fabricated with an organic or inorganic adjuvant, which is pharmacologically acceptable, of a forming agent. As examples of such an adjuvant, one can cite the following.

For preparations in the form of tablets, capsules, and sugar-coated preparations, one uses microcrystalline cellulose, calcium phosphate, diatomaceous earth, sugars such as glucose, lactose, or mannitol, talc, stearic acid, starch, sodium bicarbonate, and/or gelatin; for the product in the form of a suppository, one uses a natural oil, hardened oil, or wax, and for the preparation for inhalation, one uses crude lactose. The active component is preferably in the form having a mass median diameter of 0.01-10 microns. The product of this invention could contain the proper preservative, stabilizer, wetting agent

solubilizer, sweetener, colorant, and fragrance. Also, the product could be sealed in a slow-releasing vehicle. It is preferable to use a product vehicle by which the orally ingested product is slowly released in the gastrointestinal tract.

It is preferable that R_1-R_4 contain 1-6 carbon atoms, or most preferably 1-4 carbon atoms (when carbon atoms are contained).

The compounds used as the active components of this invention are:

4,6-dioxo-5,10-dimethyl-4H,6H-benzo[3,2-g]dithiopyran-2,8-dicarboxylic acid,

4-[5-(2-hydroxypropyloxy)-4-oxo-4H-1-benzopyran-2-yl]benzoic acid,

6,7,8,9-tertrahydro-4-oxo-10-(2-hydroxypropyl)-4H-naphtho[2,3-b]pyran-2-carboxylic acid,

6,7,8,9-tetrahydro-10-(2,3-dihydroxypropyl-1-yl)-4-oxo-4H-naphtho[2,3-b]pyran-2-carboxylic acid,

7,8,9,10-tetrahydro-5-hydroxy-4-oxo-6-propyl-4H-naptho[1,2-b]-pyran-2-carboxylic acid, and their pharmacologically acceptable salts such as sodium salts.

The treatment dose is varied, naturally depending on the symptoms, their severity, and the location of the lesion. Also, the treatment dose is varied according to the type of active component and the mode of administration. In general, the daily dose is 0.1-4000 mg and is given divided, 15-30 minutes before a meal. It is preferable to administer the drug four times daily, before three meals and before bedtime. However, under some conditions, administration ten times a day is possible.

Proof has been obtained by many standard biological tests and pharmacological tests in regard to inhibition to the enzymatic reduction of aldoses and the amelioration of the complications of chronic diabetes mellitus by the active component. They are:

(1) Determination of inhibitory activity on the reduction of aldoses by the isolated aldose reductase.

(2) Determination of inhibition of sorbitol accumulation in the sciatic nerve of rats acutely administered streptozocin (rats made acutely diabetic).

(3) Determination of activity to decrease the already enhanced sorbitol level in the sciatic nerve and the lens of the eye in the chronic diabetic rats by the prolonged administration of streptozocin.

(4) Determination of ability to inhibit or prevent the formation of galactitol in a rat with acute galactosemia.

(5) Determination of ability to delay the formation of cataracts and to increase the transparency of the lens in rats with chronic galactosemia.

The invention is explained with the following application examples, but the invention is by no means limited by these examples.

Application Example A

Activity of inhibiting the reducing enzyme

The aforementioned active component is tested in regard to the ability to decrease or inhibit the aldose reduction enzyme according to the process described in U.S. Patent No. 3,821,383 which was based on the method by Hayman et al. (Journal of Biological Chemistry, 240: 877, 1965). The substance [sic; enzyme] used was an aldose reduction enzyme partially purified from the lens of a calf. The drug was added to 10^{-4} M to determine the degree of inhibition of the enzyme activity in comparison with the control without the drug and at various levels to determine the value of IC_{50}.

Application Example B

Inhibition of sorbitol accumulation

A test was performed to determine the ability of the active component to decrease or to inhibit the accumulation of sorbitol in the sciatic nerve of a rat administered streptozocin (or made diabetic) according to the procedure described in U.S. Patent No. 3,821,383. A determination was performed on the amount of accumulated sorbitol 27 hours after the induction of diabetes in the present study. The compound was orally administered at the proper doses 4, 8 and 24 hours after streptozocin [sic]. The result was expressed in terms of % inhibition with respect to the control which did not receive any compound. In the control

without treatment, the sorbitol content was increased to 400 mmol/g tissue, 27 hours after the induction of diabetes, from the normal value of 50-100 mmol/g tissue.

Application Example C

Aldose reduction enzyme from human placenta

1 kg of placenta was homogenized in 2 L of a 25 mM phosphate buffer at pH 6.4 and the homogenate was centrifuged at 17,000 for 30 minutes. The outflow [sic; supernatant] was passed through a Con A-Sepharose column to obtain a human placenta homogenate solution.

Preparation of a column

15 g of AH-Sepharose 4B, which had been swollen in 200 mL of a 0.5M sodium chloride solution, then washed with 3 L of distilled water over a glass fiber, were added to 100 mL of a water-dioxane (1:1) mixture which contained 2.0 g of 4-carboxybenzaldehide. 1.88 g of 1-ethyl-3-(3-dimethylaminopropyl)-carbodiimide hydrochloride salt dissolved in 10 mL of water were added to this slurry dropwise. Since the mixture immediately became turbid. 30 mL of tetrahydrofuran were added further. The mixture was placed over a shaker at room temperature and for the first hour, the pH of the mixture was maintained below 5.0. 72 hours later, the transparent mixture was washed with 250 mL of water dioxane mixture (1:1) twice, then with 2 L of water, followed by washing with 250 mL of a buffer at

pH 4. The Sepharose combined with the chemical was washed with a (standard) buffer of pH 6.2 and a Pharmacia K 16/40 column was filled with the Sepharose.

Preparation of human placenta aldose-reduction enzyme

125 mg of sugar alcohol and 1,000 mL of a saturated ammonium sulfate solution were added to 1,500 mL of a placenta solution. After being left standing for 30 minutes, the solution was centrifuged at 45,000 for 10 minutes, then 250 mL of saturated ammonium sulfate solution were added to the supernatant. After being left standing for 30 minutes, the solution was centrifuged and 427 g of ammonium sulfate powder were added to the supernatant. The mixture was left standing, then centrifuged. The precipitate obtained (at 50-70% saturation) was dissolved in a minimum volume of the standard buffer solution and was then dialyzed twice against 6 L of standard buffer. The solution was frozen in liquid nitrogen for storage. A part of this solution was added to the column described above and the column was eluted with the standard buffer solution with the concentration gradient prepared with a 1M NaCl solution to obtain the enzyme.

Preparation of aldose reduction enzyme from the lens of a rat

Rats of the Sprague-Dawley strain with body weights of 125-150 g were sacrificed with carbon dioxide; after the eyes were enucleated, the lenses were carefully extirpated to be homogenized in cold distilled water (0.4 mL/lens). The homogenate was centrifuged at 10,000 rpm for 10 minutes.

The aldose-reduction enzyme activity in the supernatant was spectrophotometrically determined by recording the NADPH concentration decrease at 340 nm using a Gilford 2400-2 double-beam spectrophotometer with automatic compensation. The reaction mixture (1.00 mL) contained a phosphate buffer (about 0.1 M), NADPH (0.104 mM), and glyceraldehyde (10 mM). The blank contained all of the components except glyceraldehyde as the substrate. Proper control was carried out to compensate for the nonspecific reduction [sic; oxidation] of NADPH and absorbance due to the inhibitor. The % inhibition of each compound was calculated by a comparison of the reaction velocity observed with the substrate and the compound with the velocity observed with the substrate only. The value of IC_{50} was also calculated. The average velocity of the control was 1.72 ± 0.52 ng/mL/min. The protein concentration was spectrophotometrically determined according to the method of Bradford described in Analyt. Biochem. 72: 248-254, 1976, calculated according to Kalcker's equation (J. Biol. Chem. 167, 461-475, 1947):

$$1.45\ A_{280} - 0.74\ A_{260} = \text{mg/mL}$$

APPENDIX 16

Reissue Declaration of Alison Blakey

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application for Reissue of: Patent No. 5,443,833		§	
Patentees:	ANDREW R. CLARK PAUL WRIGHT JULIA H. RATCLIFFE	§ § §	Attorney Docket No.: 2553.004
Assignee:	Fisons, plc	§	
Issued:	August 22, 1995	§	
For:	PHARMACEUTICAL COMPOSITIONS	§	

REISSUE DECLARATION OF ALISON BLAKEY UNDER 37 C.F.R. 1.175(b)

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

As one of the attorneys who prosecuted the applications which ultimately issued as U.S. Patent No. 5,443,833 on August 22, 1995, I hereby declare:

1. My residence, post office address and citizenship are as stated below, underneath my name.

2. I was employed by Fisons plc ("Fisons") from October 1990 to May 1995 as a trainee patent attorney.

3. From January, 1991 I was the primary in-house attorney involved in the

prosecution of U.S. Serial Application 08/082,804, a continuation of U.S. Serial Application 07/742,574, which was a continuation of U.S. Serial Application 07/410,020, which was a continuation of 07/133,520 (collectively referred to as "the application").

4. Upon receiving the final rejection of the claims pending in U.S. Serial Application No. 08/082,804 dated October 19, 1994, which included claims directed to the treatment of various conditions including ophthalmic conditions and reversible obstructive airways disease (ROAD), i.e. claim 18, I instructed the United States associate of Marshall, O'Toole, Gerstein, Murray & Borun to cancel those pending claims and add claims directed solely to a method of treatment of ROAD. In accordance with this instruction, the law firm of Marshall, O'Toole, Gerstein, Murray & Borun filed an Amendment after final rejection having a Patent and Trademark mailroom stamp dated February 16, 1995 which canceled the pending claims, including claim 18, and presented three new claims limited to a method of treating a ROAD.

5. In early 1995, the Research and Development function of Fisons was acquired by Astra Pharmaceuticals Limited (Astra). As a result of this acquisition, on May 24, 1995, all Fisons in-house patent attorneys transferred to Astra. As Fisons was left with no in-house patent attorneys, responsibility for this file and others was transferred in May, 1995 to the law firm of Lewis and Taylor in Great Britain. Later in 1995, Fisons was acquired by Rhône-Poulenc Rorer (RPR).

6. It was my usual practice, and that of Fisons, that when claims in a pending patent application were limited to one aspect of the invention and such claims were allowed, and other aspects of the previously submitted claims had been canceled, to ask the United States associate to file a continuing application before the subject matter issued as a patent. In this case, I did not

make such a request to the U.S. associate before I left the employment of Fisons in May 1995. Further, it appears that no one else acted on this omission and hence the United States associate was not instructed to file a continuing application. Thus, continuing prosecution of the ophthalmic invention was not progressed.

7. It appears that in the months immediately preceding issue of U.S. Patent No. 5,443,833, when the responsibility for prosecution of the application changed, a continuing application was not sought. In early 1995, two of the three inventors, Julia Ratcliffe and Andrew Clark were no longer in the employ of Fisons. The third inventor, Paul Wright, was engaged in other research projects with Fisons and on May 24, 1995 he too transferred to Astra. The inventors were not aware of the cancellation of the pending claims and submission of the new claims in the Amendment after the Final Rejection.

8. Even though the United States and Patent and Trademark Office examiner's Final Rejection did not cite prior art specifically directed to methods of treating various ophthalmic diseases and controlling the symptoms of various ophthalmic conditions, I requested that the pending claims be canceled and the new claims be added. The claims related to methods of treatment of ROAD were of primary importance to Fisons. At the time the response to the final rejection was filed, it was seen as particularly important to obtain claims related to methods of treatment of ROAD since Fisons was in the process of filing an NDA for nedocromil sodium nebulizer solution and a granted patent issuing from U.S. Serial Application No. 08/082,804 would benefit from a term of 17 years from grant.

9. I verily believe, as a result of the circumstances described above, the original patent is wholly or partly inoperative or invalid by reason of the patentees claiming less than they

had a right ZENECA IPD Specifically, the original patent is limited to the use of the aqueous pharm solution for treating ROAD and does not cover treating and controlling the symptoms of ophthalmic conditions, support for which can be found in the specification as originally filed.

10. This error arose entirely from inadvertence, accident and mistake and without any fraudulent and/or deceptive intent on my part, or, on my best information and belief, without any fraudulent and/or deceptive intent on the part of anyone associated with me.

I declare further that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application of any patent issuing thereon.

Alison Blakey

Alison Blakey
Address: Orchardleigh Cottage
Bigfrith Lane
Cookham Dean
Berkshire SL6 9PH
Citizenship: Great Britain

Dated: August 21, 1997

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